

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 11, 2011

Table of Contents

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2010

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)*

**Delaware**  
*(State or other jurisdiction of*

**33-0728374**  
*(IRS Employer*

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

*(incorporation or organization)*

*(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)*

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of Each Class:</b>	<b>Name of Each Exchange on Which Registered:</b>
Common Stock, \$.001 Par Value	The NASDAQ Stock Market LLC
Preferred Shares Purchase Rights	

**Securities Registered Pursuant to Section 12(g) of the Act:**

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a 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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2010 as reported on the NASDAQ Capital Market, was approximately \$142,099,406. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 8, 2011, the registrant had outstanding 115,689,769 shares of common stock.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Definitive Proxy Statement for the registrant's 2011 Annual Meeting of Stockholders are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

**Table of Contents**

**INDEX**

**DYNAVAX TECHNOLOGIES CORPORATION**

	<b>Page No.</b>
<b><u>PART I</u></b>	
Item 1. <u>BUSINESS</u>	3
Item 1A. <u>RISK FACTORS</u>	17
Item 1B. <u>UNRESOLVED STAFF COMMENTS</u>	30
Item 2. <u>PROPERTIES</u>	30
Item 3. <u>LEGAL PROCEEDINGS</u>	31
Item 4. <u>(REMOVED AND RESERVED)</u>	31
<b><u>PART II</u></b>	
Item 5. <u>MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	32
Item 6. <u>SELECTED FINANCIAL DATA</u>	33
Item 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	34
Item 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	44
Item 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	45
Item 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	75
Item 9A. <u>CONTROLS AND PROCEDURES</u>	75
Item 9B. <u>OTHER INFORMATION</u>	78
<b><u>PART III</u></b>	
Item 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	79
Item 11. <u>EXECUTIVE COMPENSATION</u>	79
Item 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	79
Item 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	79
Item 14. <u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	79
<b><u>PART IV</u></b>	
Item 15. <u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	79
<u>SIGNATURES</u>	83

---

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our business strategy and regulations, our future research and development and intellectual property position, our product development efforts, our ability to commercialize our product candidates, the timing of the introduction of our products, the effect of GAAP accounting pronouncements, the potential for entry into collaborative arrangements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations and intentions. These statements appear throughout our document and can be identified by the use of forward-looking language such as may, will, should, expect, plan, anticipate, believe, estimate, predict, future, intend, or certain or the negative or variations or comparable terminology.*

*Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in Item 1A Risk Factors and Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this document. No assurance can be given that the risk factors described in this Annual Report on Form 10-K are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.*

*This Annual Report on Form 10-K includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners.*

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Dynavax Technologies Corporation ( Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine and hepatitis C and hepatitis B therapies; and preclinical programs partnered with GlaxoSmithKline ( GSK ) and AstraZeneca. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory and immunoregulatory sequences. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2001. Our principal offices are located at 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. Our telephone number is (510) 848-5100.

**Immunostimulatory Sequences (ISS)**

Our proprietary technology platform includes ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease. ISS activate the innate immune response by specifically targeting TLR9, which is found on a specialized subset of immune cells.

**Table of Contents**

ISS work by changing or reprogramming the immune responses that cause disease rather than just treating the symptoms of the disease. Since TLR9 is found only in a specialized subset of dendritic cells, ISS do not cause a generalized activation of the immune system and redirect the response of only those T cells involved in a given disease. When linked to or combined with antigens, ISS help generate memory Th1 cells that can reprogram the immune system to induce long-lasting therapeutic effects.

We have developed a number of proprietary ISS compositions and formulations that make use of the different ways in which the innate immune system responds to ISS. Depending on the indication for which ISS is being explored as a therapy, we use ISS in different ways.

**ISS Linked to or Combined with Antigens**

For prevention of infectious diseases, ISS can be linked to or combined with antigens to increase the visibility of the antigen and stimulate an immune response that will attack and destroy infected or abnormal cells. This treatment induces a highly specific Th1 immune response and generates memory T cells for long-term protection. This treatment has the potential to be used synergistically with other therapies.

**ISS Alone**

For treatment of viral and respiratory diseases, ISS can be used alone to modify the course of the disease by reprogramming the immune system. ISS suppress the Th2 inflammatory response caused by any number of allergens to modify the underlying cause of inflammation as well as provide symptomatic relief.

**Advanced ISS Technologies**

For several programs, we use our advanced proprietary knowledge to design modifications of the molecular structure of ISS to significantly increase their versatility and potency, allowing use of less ISS. These second-generation ISS stimulate specific immune responses, including potent interferon-alpha induction.

**Immunoregulatory Sequences (IRS)**

Our proprietary technology platform includes IRS, which are short DNA sequences that specifically inhibit TLRs associated with autoimmune and inflammatory diseases. TLRs are key receptors of the innate immune system that can induce strong inflammatory responses. In animal studies as well as in-vitro, our TLR inhibitors have demonstrated broad potential in multiple autoimmune diseases models, such as lupus, inflammatory skin disorders, and rheumatoid arthritis.

**Development Programs**

Our pipeline of product candidates includes:

<b>Product Candidate</b>	<b>Clinical Indication(s)</b>	<b>Phase</b>	<b>Partnership/Funding Support</b>
HEPLISAV	Hepatitis B prevention	Phase 3	Dynavax
Universal Flu vaccine	Influenza prevention	Phase 1b	Novartis (Supply and Option Agreement)
SD-101	Hepatitis C infection	Phase 1b	Dynavax
DV-601	Hepatitis B infection	Phase 1b	Dynavax
AZD1419	Asthma	IND Ready	AstraZeneca AB
DV1179	Autoimmune and inflammatory diseases	IND Ready	GlaxoSmithKline; NIH

---

**Table of Contents**

**HEPLISAV Hepatitis B Vaccine**

Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. Our global strategy is to develop HEPLISAV for adults who are at risk of hepatitis B infection, initially in populations that are less responsive to current licensed vaccines, including adults over 40 years of age, individuals with chronic kidney disease, diabetics and others.

Dynavax has worldwide commercial rights to HEPLISAV, which is based on our proprietary ISS that specifically target TLR9 to stimulate an innate immune response. This vaccine combines our first generation 1018 ISS with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax Europe facility in Düsseldorf, Germany.

HEPLISAV is being evaluated in Phase 3 trials that are directed toward fulfilling licensure requirements in the United States, Canada and Europe. The ongoing large-scale Phase 3 lot-to-lot consistency and safety trial is expected to be completed in May 2011, after a 12-month follow-up of these subjects. Enrollment for the Phase 3 trial in chronic kidney disease patients was completed in January 2011. There have been four safety assessments made by an independent data safety monitoring board, all of which have recommended the trials continue without protocol modification. In February 2011 following completion of the fourth planned safety assessment, the DSMB determined that no other formal meetings of the DSMB are required.

***Clinical Results***

Over 4,000 individuals have been vaccinated with HEPLISAV to date. In the largest completed clinical trial, known as PHAST (Phase 3 Heparin Short-regimen Trial), HEPLISAV met its primary endpoint. The multi-center PHAST trial evaluated more than 2,000 subjects from 11 to 55 years of age in Canada and Germany. This Phase 3 trial evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month, compared to a three-dose regimen of Engerix-B® administered at 0, 1, and 6 months. The primary endpoint was the proportion of subjects who developed protective antibody to hepatitis B after receiving a full course of vaccination.

Immunogenicity results from this trial demonstrated that subjects receiving HEPLISAV were seroprotected with fewer doses and at an earlier time point than subjects receiving Engerix-B. Results showed 95% of subjects who received two doses of HEPLISAV at 0 and 1 month developed protective antibody to hepatitis B by 12 weeks, compared to 81% of subjects who received three doses of Engerix-B at 0, 1, and 6 months at 28 weeks. Data from this trial also demonstrate that subjects over 40 years of age receiving two doses of HEPLISAV over one month achieved a seroprotection rate of 92%, compared to 75% of subjects receiving 3 doses of Engerix-B over six months.

Overall safety results in the PHAST trial showed the profile of 2 doses of HEPLISAV appeared similar to 3 doses of Engerix-B, with the exception that subjects who received HEPLISAV had a higher risk of developing injection site swelling, redness, and pain compared to those who received Engerix-B. The incidence of Adverse Events (AE) was 81.9% for the HEPLISAV group, compared to 81.4% for the Engerix-B group. The incidence of Serious Adverse Events (SAEs) was 1.5% for the HEPLISAV group, compared to 2.1% for the Engerix-B group. There were two cases of systemic vasculitis reported as SAEs in this trial, a case of Wegener's granulomatosis, or c-ANCA vasculitis, in the HEPLISAV group and a case of p-ANCA systemic vasculitis in the Engerix-B group. From March 2008 until September 2009, the two Investigational New Drug (IND) applications for HEPLISAV were placed on clinical hold by the U.S. Food and Drug Administration (the FDA) following the Wegener's granulomatosis SAE that occurred in the HEPLISAV group of the PHAST trial. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease.

In October 2010, we reported that HEPLISAV given as two doses over four weeks demonstrated superior seroprotection in persons with diabetes mellitus compared to Engerix-B given as three doses over 24 weeks. The subset analysis of 62 adults with diabetes in our previously reported PHAST Phase 3 multicenter study showed

## **Table of Contents**

that at 12 weeks, 84% of adult diabetics treated with HEPLISAV achieved seroprotection as compared to 0% of adult diabetics treated with Engerix-B. At week 28, 93% of the HEPLISAV-treated group versus 35% in the Engerix-B group achieved seroprotection. HEPLISAV's significantly higher rate of seroprotection was achieved without further immunization past four weeks while the Engerix-B group received a third immunization at 24 weeks.

### ***Commercial Opportunity***

Hepatitis B is a chronic disease which can lead to cirrhosis of the liver and hepatocellular carcinoma. There is no cure for hepatitis B and disease prevention through effective vaccines is critical to reducing the spread of the disease. Available hepatitis B vaccines for adults have several limitations, including:

Slow onset of protection – the current regimen for adults is usually 3 doses given over 6 months to provide seroprotection of approximately 30%, 75%, and 90% after the first, second, and third doses respectively;

Poor protection in populations that are low responders – current vaccines provide less seroprotection to persons over 40 years of age and to immunocompromised persons, such as end-stage renal disease (ESRD) patients; and

Poor compliance – in certain settings only 30% of people receive all 3 doses.

HEPLISAV is designed to address the limitations of current vaccines by providing rapid and superior protection with fewer doses than currently licensed vaccines.

We estimate the current worldwide market for adult monovalent hepatitis B vaccines exceeds \$400 million annually. This market is primarily comprised of GSK's Engerix-B and Merck's Recombivax-HB. Over an estimated \$400 million in additional sales are generated by GSK's combined Hepatitis A / Hepatitis B vaccine, Twinrix. Key market segments include chronic kidney disease (CKD) patients, healthcare workers and first responders, travelers, people with multiple sexual partners or injection drug use, and chronic liver disease patients.

HEPLISAV is being developed initially for patients less responsive to current licensed vaccines, including patients over 40 years of age, individuals with CKD, HIV, and chronic liver disease. The CKD market is large, growing rapidly, and is recommended for vaccination. In 2008, there were approximately 750,000 ESRD patients in the United States and major European markets and approximately 150,000 new patients are added annually. Because these patients typically do not respond well to current vaccines, a typical regimen calls for 8 doses of Engerix-B (versus 3 doses in the general population). Even with this regimen, approximately 35% of these immunocompromised ESRD patients do not respond to vaccination and approximately 27-43% require boosters. As vaccination for these patients occurs regularly at dialysis centers, this is a concentrated, renewable market that can be served by cost-effective, targeted sales distribution networks.

In addition to the CKD market, we believe that the potentially differentiating characteristics of HEPLISAV can address key unmet needs in adult hepatitis B vaccination, and may provide an opportunity for growth in under-served market segments such as HIV and chronic liver disease. The HIV positive market segment shares similar characteristics to the ESRD market. Vaccination is critical due to substantially increased morbidity and mortality from co-infection with HIV and HBV and similar modes of transmission. Because these patients typically do not respond well to current vaccines, aggressive vaccination regimens and boosters are common. There are approximately two million adults living with HIV in the United States and Europe, with approximately 150,000 new cases annually. Chronic liver disease can be caused by hepatitis C infection, alcohol or genetics. These patients are also recommended for vaccination, but vaccine coverage rates are low, representing a future opportunity for hepatitis B vaccines to grow.



## **Table of Contents**

We also believe that the profile of HEPLISAV has potential benefits for individuals who need rapid protection against hepatitis B, including healthcare workers, first responders, travelers and diabetics because HEPLISAV provides higher levels of protection following 30 days of treatment compared to 6 months for current licensed vaccines.

### **Universal Flu Vaccine**

Our Universal Flu vaccine is designed to offer protection against divergent strains as well as increase the efficacy and potentially reduce the antigen content of standard flu vaccines. This unique approach is based on our proprietary component N8295, which is a fusion protein comprised of two highly conserved influenza antigens, nucleoprotein (NP) and matrix protein 2 (M2e), covalently linked to proprietary second-generation TLR9 agonist. N8295 is then combined with a conventional flu vaccine:

Conventional flu vaccines Currently available flu vaccines typically contain antigens of three flu viruses: two influenza A subtypes and one influenza B subtype. The exact composition changes every year and is determined by the World Health Organization (WHO) and FDA based upon surveillance and estimates of which types and strains of viruses are likely to circulate. The goal of existing vaccines is to induce the development of antibodies to provide protection against influenza infection. Our proprietary component could be combined with any flu vaccine, including standard trivalent influenza vaccine (TIV) and vaccines for emerging strains such as H5N1 or H1N1.

Two highly conserved antigens, NP and M2e, are expected to offer protection against divergent influenza strains Our Universal Flu vaccine includes two conserved antigens, NP and M2e, which are present in all flu strains. NP, or nucleoprotein, is highly conserved across human and animal strains, while M2e, the extracellular domain of the matrix 2 protein, is conserved but with some variations among species. NP induces cytotoxic T-cell protection and M2e induces antibodies that may provide protection against divergent strains.

Our proprietary second-generation TLR9 agonist may enhance efficacy and enable antigen-sparing, which could extend the quantity of standard flu vaccine available.

Dynavax has established a worldwide supply and option agreement with Novartis Vaccines and Diagnostics, Inc., under which Novartis is supplying trivalent influenza vaccine, an essential component of our Universal Flu vaccine.

### ***Clinical Results***

In early December 2010, we reported safety and immunogenicity data from our Phase 1a clinical trial of N8295. The trial assessed three dose levels of N8295 in a total study population of 39 subjects. The Phase 1a data showed that all doses were safe and generally well tolerated. There were no dose limiting toxicities, subjects demonstrated positive antibody responses to M2e and NP, and positive T-cell mediated responses to NP were seen. Based on preliminary safety data for the Phase 1a trial, we initiated a Phase 1b study in September 2010 to evaluate the safety of the combination of N8295 and an investigational H5N1 avian influenza vaccine. The Phase 1b study evaluated 54 subjects, including 39 from the Phase 1a dose escalation study of N8295 and 15 from the Phase 1b dose escalation study of H5N1/N8295. Data from the Phase 1a and the Phase 1b study reported at the World Health Organization 7th Meeting on Evaluation of Pandemic Influenza Prototype Vaccines in February 2011 showed:

N8295 alone or combined with H5N1 vaccine was very safe and generally well tolerated;

The most common adverse events were mild, self-limited injection site reactions;

There were no SAEs;

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

All N8295 dose groups had an antibody response to M2e, and the placebo group did not;

All N8295 dose groups had an antibody response to NP, and the placebo group did not;

---

## **Table of Contents**

All N8295 dose groups had a cellular immune response to NP, and the placebo group did not;

The addition of N8295 to a non-immunogenic dose of H5N1 vaccine resulted in H1 responses in all N8295 dose groups.<sup>1</sup>

### ***Commercial Opportunity***

Human viral influenza is an acute respiratory disease with high morbidity and mortality that occurs in annual epidemics worldwide. There are an estimated 30,000 to 40,000 viral influenza-associated deaths per year in the United States, primarily in those over 65 years of age. Influenza pandemics occur infrequently, on average every 30 to 40 years, but it is estimated that the next pandemic could result in millions of deaths worldwide. Analysts estimate the current worldwide market opportunity for seasonal influenza vaccines to be approximately \$3 billion annually.

Standard flu vaccines can provide protection against the flu strains predicted to be prevalent during a season. The efficacy of these vaccines is often decreased by unpredictable changes in the actual strains causing influenza. Current vaccines are also least effective in those who need prevention the most, the elderly and others with weaker immune systems. Pandemic vaccination is further complicated by the need to produce large quantities of vaccine in a short time period.

Our Universal Flu vaccine candidate is designed to offer protection against divergent influenza strains, increase the efficacy of standard vaccines and potentially reduce the antigen content of vaccine to extend the quantity available during a pandemic.

### **SD-101 Hepatitis C Therapy**

SD-101, our hepatitis C therapy, has completed a Phase 1b clinical trial and is part of the portfolio of development programs that are available for partnership. This therapy utilizes a novel Type C TLR9 agonist based on our second-generation ISS. SD-101 is designed to be used in combination with current or emerging therapies to reduce hepatitis C virus (HCV) viral replication and induce a long-lasting immune response. In December 2009, we completed the acquisition of Symphony Dynamo, Inc., which provided us with full development and commercialization rights to SD-101.

Data from a Phase 1b trial and from an *in vitro* study of SD-101's mechanism of action show that SD-101 is safe and well-tolerated, and induces both IFN-lambda and IFN-alpha at concentrations producing antiviral activity.

### **DV-601 Hepatitis B Therapy**

DV-601, our proprietary hepatitis B therapy, is completing a Phase 1b clinical trial and is part of the portfolio of development programs that are available for partnership. Our treatment approach combines both the surface and core HBV antigens with ISCOMATRIX<sup>®</sup> adjuvant originally entered into development by Rhein Biotech prior to its acquisition by Dynavax in 2006. DV-601 is designed to induce an immune response against HBV-infected cells and if proven to be safe and effective, may offer an alternative therapeutic option for patients chronically infected with HBV. We have retained all commercial rights to this product.

The Phase 1b dose escalation study assessed safety and the immunologic and virologic responses in 14 subjects with chronic hepatitis B infection, including six patients that were HBeAg negative and eight patients who were HBeAg positive, and found:

The therapeutic regimen was safe and generally well tolerated at all dose levels;

Most common systemic reactions were fatigue and malaise. No SAEs were recorded;

<sup>1</sup> The Journal of Infectious Diseases 2008; 198:1309-16 and Vaccine 28 (2010) 840-848

## **Table of Contents**

DV601 was found to elicit immune responses at all dose levels, and anti-HBe antibodies were elicited in two of eight (2/8) patients;

Anti-HBs antibodies were elicited in four of 14 (4/14) patients;

Amongst the eight HBeAg positive patients, two had HBeAg clearance, and one of those individuals also had HBsAg clearance;

Three patients are still in the follow-up observation period.

### **DV1179 (IRS) for Autoimmune and Inflammatory Diseases**

We are developing DV1179, a bifunctional inhibitor of TLR7 and TLR9, under a worldwide strategic alliance with GSK. Our IRS program is focused on novel TLR inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We plan to initiate a Phase 1 clinical study with GSK in 2011.

### **AZD1419 Asthma Therapy**

We have developed AZD1419, a novel candidate drug for asthma, under our worldwide collaboration with AstraZeneca. AZD1419 utilizes our proprietary second-generation ISS and represents a new strategy for the treatment of allergic respiratory diseases such as asthma. This therapy is designed to modify the course of these diseases by changing the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms.

### **Pharmaceutical Partnerships and Other Funding Agreements**

Our objective is to discover novel therapies based on our proprietary technologies and develop a diversified pipeline of product candidates to build a product-based business. To reach this objective, an important part of our strategy is to establish partnerships with leading pharmaceutical companies and enter into funding agreements. Our pharmaceutical partners provide valuable resources, expertise, and abilities that allow us to further advance the development of our product candidate programs. We also have funding agreements with U.S. government institutions.

### **GlaxoSmithKline**

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop, and commercialize endosomal 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. We 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 royalties from the mid-single digits up to the high-teens based on product sales and have retained an option to co-develop and co-promote one specified product under the collaboration.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause, upon prior written notice within a specified window of time dependent upon stage of clinical development of the programs.

## **Table of Contents**

### **AstraZeneca AB**

In September 2006, we entered into a worldwide research and license agreement with AstraZeneca to discover and develop TLR9 agonist products for asthma and COPD. We are eligible to receive a total of \$136 million in payments and, upon commercialization of these products, royalties up to the high-teens based on product sales, if any. AstraZeneca has the right to sublicense its rights with our prior consent. We also have the opportunity to co-promote in the United States. In September 2008, we received a \$4.5 million milestone payment from AstraZeneca for the nomination of the first candidate drug, AZD1419, for asthma and have completed IND-enabling studies.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

### **Novartis Vaccines and Diagnostics, Inc.**

In July 2008, we entered into a supply and option agreement with Novartis related to our Universal Flu vaccine. Under this agreement, Novartis is supplying trivalent influenza vaccine, an essential component of our Universal Flu vaccine. We agreed to conduct early-stage development through a defined proof-of-concept. If Novartis exercises the right to negotiate and enter a further agreement for development and commercialization, we would retain co-commercialization rights in the United States and receive product royalties on product sales outside of the United States, if any. If the option is not exercised or the parties do not enter into a further agreement, Novartis remains committed to providing commercial supply of trivalent influenza vaccine with pre-agreed commercial terms and we retain the right to independently continue with late-stage development and commercialization, provided we do not partner with a company that produces or markets a trivalent influenza vaccine product in the United States.

Either party may terminate the agreement if (a) the other party commits a material uncured breach, (b) there is change in control of the other party, (c) certain specified clinical or regulatory objectives are not achieved or certain development events or failures occur, or (d) Dynavax ceases development of the product candidate for a certain length of time.

### **National Institutes of Health (NIH) and Other Funding**

In September 2008, we were awarded a \$17 million contract to develop our advanced ISS technology using TLR9 agonists as vaccine adjuvants. This five-year contract was awarded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) and supports adjuvant development for biodefense vaccines, including anthrax as well as other diseases. NIAID is funding 100% of the total \$17 million cost of our program under Contract No. HHSN272200800038C. The NIH may terminate performance of work under the contract if the Contracting Officer determines that a termination is in the government's interest or if the Company defaults in performing and fails to cure after notice.

During 2010, we announced a grant from the NIAID to take a systems biology approach to study the differences between individuals that do or do not respond to vaccination against the HBV. This study will be one of several projects covered in a five-year, \$17.6 million grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program.

We also received the award of a \$0.6 million grant from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus (HPV). In contrast to the two approved HPV vaccines that target approximately 70% of HPV strains, our goal is to develop a vaccine that provides immunity to nearly all cancer-causing strains of HPV. Each year, 470,000 new cases of cervical cancers are diagnosed worldwide, and 250,000 deaths are attributable to cervical cancers.

## **Table of Contents**

Finally, \$0.7 million in grants under The Patient Protection and Affordable Care Act of 2010 were awarded to us to cover research and development costs from 2009 and 2010 for our qualified therapeutic discovery projects including HEPLISAV.

For our TLR inhibitor programs, since 2004 we have been awarded \$2.8 million in grants from the NIH and Alliance for Lupus Research.

## **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. In addition to seeking patent protection in the United States, we generally file patent applications in Australia, Canada, Japan, Western European countries and additional foreign countries on a selective basis in order to further protect the inventions that we or our partners consider important to the development of our foreign business. We also rely on trade secrets and contracts to protect our proprietary information.

As of December 31, 2010, our intellectual property portfolio included 16 issued U.S. patents, over 100 issued or granted foreign patents and over 100 additional pending U.S. and foreign patent applications claiming compositions and formulations of ISS and IRS, their methods of use or processes for their manufacture. Some of these patents and applications are exclusively licensed to us under two agreements with the Regents of the University of California.

We have an issued U.S. patent covering the ISS contained in our HEPLISAV investigational vaccine that will expire in 2018, unless extended, and corresponding issued patents in several major European and other countries. We own or have an exclusive license to U.S. and foreign patent applications pending for each of our other product candidates and/or their uses. At present, it is not known or determinable whether patents will issue from any of these applications or what the specific expiration dates would be for any patents that do issue.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued in the United States are effective for:

the longer of 17 years from the issue date or 20 years from the earliest effective filing date, if the patent application was filed prior to June 8, 1995; and

20 years from the earliest effective filing date, if the patent application was filed on or after June 8, 1995.

In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is 20 years from the earliest effective filing date. Our patent estate, based on patents existing now and expected by us to issue based on pending applications, will expire on dates ranging from 2017 to 2030.

The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patents.

Because patent applications in the United States and many foreign jurisdictions typically are not published until 18 months after filing and publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in each of our issued

**Table of Contents**

patents or pending patent applications or that we were the first to file for protection of the inventions set forth in these patent applications. The U.S. Patent and Trademark Office may declare interference proceedings to determine the priority of inventions with respect to our patent applications and those of other parties or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies, including Pfizer, Inc., as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions owned or licensed to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use or sell any products. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. Two of our potential competitors, Merck and 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 United States, they remain in force in the United States.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. The existence of third-party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. For example, Pfizer has issued U.S. and foreign patent claims as well as patent claims pending with the U.S. Patent and Trademark Office and foreign patent offices that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of ISS. To the extent we are able to commercialize HEPLISAV in the United States while these patents remain in force, Merck, GSK or the Institut Pasteur may bring claims against us. Litigation or any other proceedings, such as patent interferences, could result in substantial costs to and diversion of effort by us, and an adverse outcome in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties, or require us to cease using some of our technology. We may not prevail in any of these actions or proceedings.

In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our policy is to require each of our commercial partners, employees, consultants and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. These agreements also generally provide that we own all inventions conceived by the individuals in the course of rendering their employment or services to us. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Under the terms of our license agreements with the Regents of the University of California, we are required to pay license fees, make milestone payments, share a portion of fees from third party partnerships up to a specified amount and pay low single-digit royalties on net sales resulting from successful products originating from the licensed technologies. To date, we have paid the University of California a total of \$1.6 million in license fees, shared third party partnership fees and milestone payments under these agreements. We estimate the total potential milestone payments payable for each such product will total approximately \$3.1 million, not

---

## **Table of Contents**

including royalties. We may terminate these agreements in whole or in part on 60 days advance notice. The Regents of the University of California may terminate these agreements if we are in breach for failure to make royalty payments, meet diligence requirements, produce required reports or fund internal research and we do not cure such breach within 60 days after being notified of the breach. Otherwise, the agreements generally continue in effect until the last patent claiming a product licensed under the agreement or its manufacture or use expires, or in the absence of patents, until the date the last patent application claiming a licensed product is abandoned.

### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many of our competitors, including biotechnology and pharmaceutical companies, academic institutions and other research organizations, are actively engaged in the discovery, research and development of products that could compete directly or indirectly with our products under development.

HEPLISAV, a two-dose hepatitis B vaccine, if approved and commercialized, will compete directly with three-dose marketed vaccines produced by GSK and Merck & Co. (Merck), among others. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in the European Union and United States. In addition, HEPLISAV will compete against a number of multivalent vaccines that simultaneously protect against hepatitis B in addition to other diseases.

Our Universal Flu vaccine, if developed, approved and commercialized, will compete with traditional and emerging influenza vaccines from companies currently marketing these products, including: GSK, Novartis, Sanofi Pasteur, MedImmune/AstraZeneca and CSL Ltd. In addition, there are several companies developing potentially competing universal vaccines for influenza, including Sanofi Pasteur, VaxInnate, Merck and Vical.

Our hepatitis C therapy, SD-101, if developed, approved, and commercialized, may compete directly with interferon alpha, products currently marketed by Roche and Merck. Other companies, such as Vertex Pharmaceuticals, Inc./Tibotec Pharmaceuticals, Gilead Sciences, Inc. (Gilead), Merck, Bristol-Myers Squibb, and Roche/Pharmasset, Inc./InterMune, Inc. are developing direct acting antiviral therapy, including NS5A inhibitors, protease inhibitors and polymerase inhibitors, and long-acting interferons. As these products may enter the market potentially within the next one to five years, combination therapy is likely to evolve. Novel therapies aim to improve the efficacy, safety and convenience of current hepatitis C treatment and may compete both directly and indirectly with SD-101.

Our hepatitis B therapy, DV-601, if developed, approved and commercialized, will compete directly with existing hepatitis B therapy products, including antiviral drugs and interferon alpha, manufactured by Roche, Merck, Gilead, Bristol-Myers Squibb, GSK, and Novartis. In addition, our hepatitis B therapy faces competition from several companies developing novel antivirals and immunomodulators, including Pharmasset and LG Life Sciences, Cytheis and Phytrix, as well as companies developing therapeutic vaccines, including Genexine Co., Ltd.

Our therapy for autoimmune and inflammatory diseases, DV1179, is a bifunctional inhibitor of TLR7 and TLR9 that if developed, approved and commercialized will compete with key biologic therapies from companies such as Genentech, Inc. (Genentech), Biogen Idec, Roche, Abbott Laboratories and Human Genome Sciences/GSK. In addition, our product would compete with generic drugs commonly used to treat autoimmune diseases, including corticosteroids, NSAIDs, antimalarials and immunosuppressive agents. Other companies, such as MedImmune, Genentech, Idera, Pfizer and UCB/Immunomedics, Inc., are developing anti-IFN-alpha-antibodies, B-cell targeted antibodies, immunosuppressants, and other TLR inhibitors that may compete directly with our product candidate.

Our asthma therapy, AZD1419, if developed, approved and commercialized, will compete indirectly with existing asthma therapies, such as inhaled beta-agonists, corticosteroids, leukotriene inhibitors and IgE



## **Table of Contents**

monoclonal antibodies, including those marketed by Merck, Genentech, Novartis, AstraZeneca and GSK. In addition, directly competing products are in development by Sanofi-Aventis and Idera Pharmaceuticals.

Many of the entities developing and marketing these competing products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly for collaborative agreements with large, established companies and access to capital. These entities may also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to or necessary for our programs.

## **Regulatory Considerations**

The advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of our potential products are subject to extensive regulation by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical and biological products are subject to rigorous review by the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations. The steps ordinarily required by the FDA before a new drug or biologic may be marketed in the United States are similar to steps required in most other countries and include but are not limited to the following:

completion of preclinical laboratory tests, preclinical studies and formulation studies;

submission to the FDA of an IND application for a new drug or biologic which must become effective before clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug or biologic for each proposed indication;

demonstration of the consistent manufacturing of a drug substance and drug product;

the submission of a new drug application ( NDA ) or a biologics license application ( BLA ) to the FDA; and

FDA review and approval of the NDA or BLA before any commercial marketing, sale or shipment of the drug.

If we do not comply with applicable requirements, U.S. regulatory authorities may fine us, require that we recall our products, seize our products, require that we totally or partially suspend the production of our products, refuse to approve our marketing applications, criminally prosecute us, and/or revoke previously granted marketing authorizations.

To secure FDA approval, we must submit extensive non-clinical and clinical data, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and other supporting information to the FDA for each indication. The number of preclinical studies and clinical trials that will be required for FDA and foreign regulatory agency approvals varies depending on the product candidate, the disease or condition for which the product candidate is in development and regulations applicable to any particular drug candidate. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval or clearance. Further, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. In addition, the development of the drug substance and drug product may require manufacturing modifications to ensure future regulatory acceptance. The approval process takes many years, requires the expenditures of substantial resources, involves post-marketing surveillance and may involve requirements for additional post-marketing studies. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. The FDA may withdraw product approvals if we do not continue to comply with regulatory standards



## Table of Contents

or if problems occur following initial marketing. Delays experienced during the governmental approval process may materially reduce the period during which we will have exclusive rights to exploit patented products or technologies. Delays can occur at any stage of drug development and as a result of many factors, certain of which are not under our control, including but not limited to the following:

lack of efficacy, or incomplete or inconclusive results from clinical trials;

unforeseen safety issues;

failure by investigators to adhere to protocol requirements, including patient enrollment criteria;

slower than expected rate of patient recruitment;

failure by subjects to comply with trial protocol requirements;

inability to follow patients adequately after treatment;

inability to qualify and enter into arrangements with third parties to manufacture sufficient quality and quantities of materials for use in clinical trials;

failure by a contract research organization to fulfill contractual obligations; and

adverse changes in regulatory policy during the period of product development or the period of review of any application for regulatory approval or clearance.

Non-clinical studies involve laboratory evaluation of product characteristics and animal studies to assess the initial efficacy and safety of the product. The FDA, under its good laboratory practices regulations, regulates non-clinical studies. Violations of these regulations can, in some cases, lead to invalidation of those studies, requiring these studies to be repeated. The results of the non-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application, which must be approved by the FDA before we can commence clinical investigations in humans. Unless the FDA objects to an IND application, the IND application will become effective 30 days following its receipt by the FDA. Clinical trials involve the administration of the investigational product to humans under the supervision of a qualified principal investigator. We must conduct our clinical trials in accordance with good clinical practice under protocols submitted to the FDA as part of the IND application. In addition, each clinical trial must be approved and conducted under the auspices of an investigational review board and with patient informed consent. The investigational review board will consider, among other things, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial.

The stages of the FDA regulatory process include research and preclinical studies and clinical trials in three sequential phases that may overlap. Research and preclinical studies do not involve the introduction of a product candidate in human subjects. These activities involve identification of potential product candidates, modification of promising candidates to optimize their biological activity, as well as preclinical studies to assess safety and effectiveness in animals. In clinical trials, the product candidate is administered to humans. Phase 1 clinical trials typically involve the administration of a product candidate into a small group of healthy human subjects. These trials are the first attempt to evaluate a drug's safety, determine a safe dose range and identify side effects. During Phase 2 trials, the product candidate is introduced into patients who suffer from the medical condition that the product candidate is intended to treat. Phase 2 studies are designed to evaluate whether a product candidate shows evidence of effectiveness, to further evaluate dosage, and to identify possible adverse effects and safety risks. When Phase 2 evaluations demonstrate that a product candidate appears to be both safe and effective, Phase 3 trials are undertaken to confirm a product candidate's effectiveness and to test for safety in an expanded patient population. If the results of Phase 3 trials appear to confirm effectiveness and safety,

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

the data gathered in all phases of clinical trials form the basis for an application for FDA regulatory approval of the product candidate.

We and all of our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practice (GMP) regulations. Manufacturers of biologics also must comply with FDA's general

## **Table of Contents**

biological product standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Good manufacturing practice regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation. Prior to granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. In addition, our facilities are subject to periodic inspections by the FDA for continued compliance with GMP requirements during clinical development as well as following product approval. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization and pricing or reimbursement approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, manufacturing, marketing authorization, pricing and reimbursement vary widely from country to country.

At present, foreign marketing authorizations may be applied for at a national level, although within the European Union centralized registration procedures are mandatory for biotechnology and some other drugs and are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use.

We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

## **Research and Development**

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were \$53.6 million, \$38.7 million and \$44.8 million for the years ended December 31, 2010, 2009 and 2008, respectively.

## **Environment**

We have made, and will continue to make, expenditures for environmental compliance and protection. We do not expect that expenditures for compliance with environmental laws will have a material effect on our capital expenditures or results of operations in the future.

## **Employees**

As of December 31, 2010, we had 128 full-time employees, including 21 Ph.D.s, 5 M.D.s and 10 others with advanced degrees. Of the 128 employees, 100 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement, and we believe our relations with our employees are good.

## **Available Information and Website Address**

Our website address is [www.dynavax.com](http://www.dynavax.com). We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the SEC's website directly to our reports. The contents of our website are not incorporated by reference into this report.

---

**Table of Contents**

**ITEM 1A. RISK FACTORS**

This Annual Report on Form 10-K contains forward-looking statements concerning our future products, product candidates, timing of development activities, regulatory strategies, intellectual property position, 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.

**Risks Related to our Finances and Capital Requirements**

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$316.9 million as of December 31, 2010. 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 in future years as a result of our investment in research and development activities.

We do not have any products that generate revenue. 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 development efforts will be sufficient to support approval of HEPLISAV; or whether the market for HEPLISAV will be sufficient for us to reach profitability.

Clinical trials for certain of our other product candidates are ongoing, and our other product candidates may never be commercialized or achieve profitability. Our ability to generate revenue depends upon demonstrating in clinical trials that our product candidates are safe and effective, 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 than favorable terms. Additionally, if we continue to incur substantial additional net losses without additional equity funding, we will continue to deplete our stockholders' equity, and if such equity balance falls below the listing requirement threshold of \$2.5 million for the NASDAQ Capital Market, we may be delisted.

*We require substantial additional capital to continue development of our product candidates, in particular our most advanced candidate, HEPLISAV. We cannot be certain that funds will be available and, if they are not available, we may not be able to continue as a going concern which may result in actions that could adversely impact our stockholders.*

In order to continue development of our product candidates, particularly HEPLISAV, we still need to raise significant additional funds. This may occur through our September 2010 Purchase Agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"), future public or private financings and/or strategic alliance and licensing arrangements. We expect to continue to spend substantial funds in connection with:

development and manufacturing of our product candidates, particularly HEPLISAV;

various human clinical trials for our product candidates; and

protection of our intellectual property.

## **Table of Contents**

We currently estimate that we will have sufficient resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents and marketable securities on hand at December 31, 2010, anticipated revenues from existing agreements and the funding available to us under the Purchase Agreement.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms, or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

***The sale of our common stock to Aspire Capital may cause dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.***

Shares offered to Aspire Capital under the Purchase Agreement may be sold over a period of up to 25 months from the date of the Purchase Agreement subject to the limitations and conditions of the agreement. The number of our shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement and the number of authorized shares we have available for sale. Aspire Capital may ultimately purchase all, some or none of the remaining common stock provided for in the Purchase Agreement. As of December 31, 2010, we have issued 2,350,000 shares of common stock under the Purchase Agreement. After Aspire Capital has acquired shares pursuant to the Purchase Agreement, it may sell all, some or none of those shares.

On any business day on which the closing sale price of our common stock exceeds \$1.00 per share, we have a right to sell up to a maximum of 150,000 shares per day under the Purchase Agreement, which total may be increased by mutual agreement up to an additional 1,000,000 shares per day. The capital available under the Purchase Agreement may not be sufficient to fund our current need for capital. The extent to which we rely on Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

Depending upon market liquidity at the time, sales of shares of our common stock by Aspire Capital may cause the trading price of our common stock to decline. In addition, sales to Aspire Capital by us pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

***Our independent registered public accountants have indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.***

Our independent registered public accounting firm has included in their audit opinion on our consolidated financial statements for the year ended December 31, 2010 a statement with respect to substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

## **Table of Contents**

### **Risks Related to our Business**

*The success of our product candidates depends on timely achievement of successful clinical results, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.*

None of our product candidates have been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the U.S. Food and Drug Administration ( FDA ) and by foreign regulatory agencies. Our success is primarily dependent on our ability to timely enroll patients in clinical trials, achieve successful clinical results, provide adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and obtain regulatory approvals for our most advanced product candidates. Approval processes in the United States and in other countries are uncertain, can 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. In addition, failure to timely and 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 approved by the relevant regulatory authority for a product may restrict to whom we may market the product, which could significantly limit the commercial opportunity for such product.

Prior to granting product approval, the FDA must determine that our or our third party contractor s manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable FDA GMP current regulations. Manufacturers of biologics also must comply with FDA s general biological product standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Good manufacturing practice regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation.

*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, failure to enroll patients in a timely manner, or delays due to manufacturing an inadequate supply of the product candidate. Even a short delay in a trial for any product candidate could require us to delay commencement or continuation of a trial until the target population is available for testing, which could result in a delay of a year or more. The FDA may require larger or additional clinical trials for our HEPLISAV product candidate than we currently expect before granting regulatory approval, if at all.



## **Table of Contents**

Our registration and commercial timelines depend on successful completion of current and planned clinical trials, successful results from such 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.

***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.

***HEPLISAV 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.***

HEPLISAV 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 investigational new drug ( 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 but the other IND application for HEPLISAV remains on clinical hold. In addition, most of our clinical product candidates contain ISS, and if a common safety risk across therapeutic areas were identified, it 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 our facility in Düsseldorf, Germany and third parties to supply materials necessary to manufacture our clinical product candidates. We have limited experience in manufacturing sufficient quantities of ISS for our clinical trials and rely on limited third parties to produce the ISS we need for our clinical trials. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. If we reduce our clinical product candidates, we may not require this manufacturing capacity.***

We rely on a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including ISS, 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 have relied on a limited number of suppliers to produce ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. If we were unable to maintain our existing source for 1018 ISS, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV. We or other third parties may not be able to produce 1018 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. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations. We may not be able to comply with these and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates and could result in significant expense. Moreover, if our HEPLISAV clinical trials are sufficient for approval and depending on the level of market acceptance of the product, we may not have the capacity in our existing facility to meet all of our commercial supply needs in the future.

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. We may also consider other alternatives for the Düsseldorf facility, including its sale or closure, which would result in certain costs of disposal or discontinuation of operations. Discontinuation of operations in Düsseldorf would be complex, expensive, time-consuming and difficult to execute without significant additional costs due to, among other things, international legal and tax considerations related to those operations. As a result, we may not realize cost savings associated with closure of the Düsseldorf operations, 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.***

We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. 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/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. 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. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. 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.

If, as a result of these inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant delays can occur if the qualification of a new supplier is required.

## **Table of Contents**

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 commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

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.

***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 United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States 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;

diverse 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 United States. 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.

***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.***

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

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.

## **Table of Contents**

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

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 United States 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 achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

***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.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments.

## **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. Failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union, may significantly impair the potential for this product and our ability to successfully develop, manufacture and commercialize HEPLISAV as a product candidate. We also will need to enter into collaborative relationships to provide funding to support our other 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, manufacturing issues, a change in business strategy, a change of control or other reasons;

our shortage of capital resources may impact the willingness of companies to collaborate with us;

our contracts for collaborative arrangements are terminable at will on written notice and may otherwise 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 have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;

our ability to generate future event payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals, successfully manufacture, 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, manufacturing, 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.

*The financial terms of future collaborative licensing or financing arrangements could result in dilution of our share value.*

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under



## **Table of Contents**

which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in dilution in the value of our issued and outstanding shares.

***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 and inflammatory 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 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, general and administrative support, 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. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific, manufacturing, sales, marketing, general and administrative and management personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives. 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.

***The loss of key personnel, including our Chief Executive Officer or our President, could delay or prevent achieving our objectives.***

Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer, Dr. Dino Dina, or our President, Dr. J. Tyler Martin. We currently have no key person insurance on any of our employees.

***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 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 clinical trial liability and umbrella insurance coverage for our clinical trials. 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 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 believe 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.

### **Risks Related to our Intellectual Property**

*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 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 obtain and 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. 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.

*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 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 and 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

## **Table of Contents**

will soon expire outside the United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States while these patents remain in force, Merck, 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, 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. 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., 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 United States, 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 United States 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 United States, 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:

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.

### **Risks Related to an Investment in our Common Stock**

*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;

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;

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

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

the 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 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. We may in the future be the target of such 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.

---

**Table of Contents**

*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.

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.

*We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.*

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial 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 registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, 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.

---

**Table of Contents**

***Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2010, we had 115,611,069 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144.

We also have filed registration statements on Form S-3 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under the Purchase Agreement, the warrants issued as part of our public offering closed in April 2010, the warrants issued to Symphony Dynamo Holdings LLC ( Holdings ) in connection with our acquisition of SDI in December 2009, and warrants issued to Deerfield Management in connection with the July 2007 Loan Agreement.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

***Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC collectively control a substantial percentage of the voting power of our outstanding common stock as well as \$15 million of our debt.***

Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, Symphony ) currently collectively control approximately 9,031,431 shares of our common stock and warrants to purchase approximately 4,515,717 shares of our common stock. Based on the number of shares of our common stock that are outstanding as of December 31, 2010, Symphony owns approximately 8% of our total outstanding shares of our common stock. If Symphony exercises all of the warrants held by it and assuming no other issuances of our common stock, Symphony would own approximately 11% of our total outstanding shares of common stock. In addition, Holdings, an affiliate of Symphony, holds a promissory note in the principal amount of \$15 million, which may be satisfied in cash, Dynavax common stock or a combination of cash and Dynavax common stock, at our election. Finally, under the terms of the Standstill and Corporate Governance Letter Agreement we entered into with Holdings on December 30, 2009, for as long as Holdings and its affiliates, which include Symphony, beneficially own 10% or more of our outstanding common stock, we agreed to use our commercially reasonable efforts to cause to be elected and remain as directors on our Board of Directors one individual designated by Holdings and a second individual who shall be an independent third party designated by Holdings and reasonably acceptable to us. Holdings designated Mark Kessel, a partner of Symphony Capital LLC, as its designee and Mr. Kessel has been appointed to our Board of Directors. On July 22, 2010, the Board of Directors nominated Daniel L. Kisner, M.D. to the Board of Directors as the independent third party designee. As a result, Symphony, Holdings and their affiliates will be able to exercise substantial influence over the direction of the Company.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

As of December 31, 2010, we lease approximately 44,000 square feet of laboratory and office space in Berkeley, California (the Berkeley Lease) under agreements expiring in September 2017. Additionally, approximately 3,000 square feet of the leased premises under the Berkeley Lease is subleased through February 2011. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.



**Table of Contents**

**ITEM 3. 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 4. (REMOVED AND RESERVED)**

**Table of Contents****PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information and Holders**

Our common stock is traded on the NASDAQ Capital Market under the symbol DVAX. Public trading of our common stock commenced on February 19, 2004. The following table sets forth for the periods indicated the high and low sale prices per share of our common stock.

	Common Stock Price	
	High	Low
<b>2010</b>		
First Quarter	\$ 1.83	\$ 1.19
Second Quarter	\$ 2.08	\$ 1.28
Third Quarter	\$ 2.34	\$ 1.58
Fourth Quarter	\$ 3.24	\$ 1.75
<b>2009</b>		
First Quarter	\$ 1.04	\$ 0.50
Second Quarter	\$ 2.19	\$ 0.64
Third Quarter	\$ 3.35	\$ 1.15
Fourth Quarter	\$ 1.94	\$ 1.11

As of March 8, 2011, there were approximately 180 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 300 as the number of record holders does not include shares held in street name through brokers.

**Dividends**

We have never paid any cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

None.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, and with the Consolidated Financial Statements and Notes thereto which are included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2010, 2009 and 2008 and the Consolidated Balance Sheets Data as of December 31, 2010 and 2009 are derived from the audited Consolidated Financial Statements included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2007 and 2006 and the Consolidated Balance Sheets Data as of December 31, 2008, 2007 and 2006 are derived from Consolidated Financial Statements that are not included in this Form 10-K. Historical results are not necessarily indicative of results to be anticipated in the future.

	2010	Years Ended December 31,			2006
		2009	2008	2007	
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ 23,950	\$ 40,318	\$ 37,094	\$ 14,093	\$ 4,847
Operating expenses:					
Research and development	53,680	38,708	44,771	65,888	50,116
General and administrative	16,879	15,745	15,463	18,293	14,836
Acquired in-process research and development <sup>(1)</sup>					4,180
Amortization of intangible assets	980	980	980	1,004	698
Total operating expenses	71,539	55,433	61,214	85,185	69,830
Loss from operations	(47,589)	(15,115)	(24,120)	(71,092)	(64,983)
Interest income	85	178	1,631	3,965	3,187
Interest expense	(1,654)	(124)	(9,157)	(1,719)	(99)
Other income (expense) <sup>(2)</sup>	(8,150)	(66)	110	200	100
Loan forgiveness <sup>(3)</sup>			5,000		
Net loss.	(57,308)	(15,127)	(26,536)	(68,646)	(61,795)
Consideration paid in excess of carrying value of the noncontrolling interest in SDI <sup>(4)</sup>		(19,671)			
Add: Loss attributable to noncontrolling interest in Symphony Dynamo, Inc.		4,233	5,707	8,675	9,743
Net loss attributable to Dynavax	\$ (57,308)	\$ (30,565)	\$ (20,829)	\$ (59,971)	\$ (52,052)
Basic and diluted net loss per share attributable to Dynavax common stockholders	\$ (0.69)	\$ (0.76)	\$ (0.52)	\$ (1.51)	\$ (1.61)
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	82,463	40,350	39,819	39,746	32,339

(1) Represents acquired in-process research and development. This amount relates to the Rhein Biotech GmbH acquisition in April 2006.

(2) Includes the impact of the anti-dilution provision associate with the common stock and warrants issued to Symphony and the change in fair value of the long-term contingent and warrant liabilities to Symphony for the year ended December 31, 2010. See Note 8 to the Consolidated Financial Statements.

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

- (3) Represents a \$5.0 million portion of the loan from Deerfield that was forgiven upon termination of the loan agreement. See Note 9 to the Consolidated Financial Statements.
  
- (4) Represents the consideration paid in excess of the carrying value of the noncontrolling interest in SDI and is treated as a deemed dividend for purposes of reporting earnings per share, increasing loss per share for the year ended December 31, 2009. See Note 8 to the Consolidated Financial Statements.

**Table of Contents**

	2010	2009	December 31, 2008 (In thousands)	2007	2006
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and marketable securities	\$ 72,154	\$ 36,720	\$ 43,367	\$ 56,617	\$ 72,831
Investments held by Symphony Dynamo, Inc.			25,109	31,631	13,363
Working capital	59,814	23,723	35,688	82,035	75,985
Total assets	84,249	50,470	90,623	120,449	102,890
Long-term note payable to Holdings.	10,939	9,342			
Noncontrolling interest in Symphony Dynamo, Inc.			2,634	8,341	2,016
Accumulated deficit	(316,945)	(259,637)	(248,743)	(227,914)	(167,943)
Total Dynavax stockholders' equity	52,111	6,376	13,522	30,790	77,056

**ITEM 7. 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, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as 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. The discussion should be read in conjunction with Item 6 Selected Financial Data and the Consolidated Financial Statements and the related notes thereto set forth in Item 8 Financial Statements and Supplementary Data.*

**Overview**

Dynavax Technologies Corporation (Dynavax or the Company), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine, hepatitis C and hepatitis B therapies; and preclinical programs partnered with GlaxoSmithKline (GSK) and AstraZeneca. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases.

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

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies, and the valuation of certain liabilities. We base our estimates on historical experience and on

## **Table of Contents**

various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to the consolidated financial statements, we believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements.

### ***Revenue Recognition***

Our revenues are derived from collaborative and service agreements as well as grants. Collaborative agreements may include upfront license payments, cost reimbursement for the performance of research and development, milestone payments, contract manufacturing services, and royalty fees. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under established accounting guidance. The different elements of the revenue arrangement are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. For agreements which do not meet the criteria of separate units of accounting under established accounting guidance, the total consideration received is grouped as one unit and the applicable revenue recognition methodology is applied to the single unit. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where we have continuing performance obligations is deferred and recognized as performance occurs. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Revenue from milestones that are contingent upon the achievement of substantive at-risk performance criteria is recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

### ***Research and Development Expenses and Accruals***

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services, and non-cash stock-based compensation. Research and development costs are expensed as incurred. For agreements with third parties for clinical trials, manufacturing and process development, research

## **Table of Contents**

and other consulting activities entered into prior to January 1, 2008, costs were expensed upon the earlier of when non-refundable amounts were due or as services were performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements entered into after January 1, 2008 are capitalized and expensed as the related goods are delivered or services are performed.

Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, completion of portions of the clinical trial, or similar conditions. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties.

### ***Stock-Based Compensation***

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option's vesting period, assuming an annual forfeiture rate of 15% for both the executive level and non-executive level employee groups, and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level and non-executive level employees were grouped and considered separately for valuation purposes. In 2008, based on employee termination data we adjusted the expected life of the options for both groups of employees to 4 years, which remains consistent for fiscal years ended December 31, 2009 and 2010. Expected volatility is based on historical volatility of our stock and comparable peer data over the life of the options granted to executive and non-executive level employees.

### ***Goodwill and Other Intangible Assets***

Goodwill is recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the acquisition method of accounting. The ongoing evaluation for impairment of goodwill requires significant management estimates and judgment. The Company operates in one segment and we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired.

### ***Impairment of Long-lived Assets***

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

significant changes in the strategy for our overall business;

significant underperformance relative to expected historical or projected future operating results;

significant changes in the manner of our use of acquired assets;

significant negative industry or economic trends;

significant decline in our stock price for a sustained period;





**Table of Contents**

a current expectation that, more likely than not, a long lived asset (asset group) will be sold or otherwise disposed of significantly before the end of its previously estimated useful life; and

our market capitalization relative to net book value.

Determination of recoverability is based on an estimate of undiscounted cash flows resulting from the use of the asset and its eventual disposition. Measurement of impairment charges for long-lived assets that management expects to hold and use are based on the fair value of such assets.

**Consolidation of Variable Interest Entities**

Arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities ( VIEs ). An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

We have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Prior to the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option on December 30, 2009, our consolidated financial statements include the accounts of SDI, a VIE, of which we were the primary beneficiary.

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

Revenues consist of amounts earned from collaborations, grants, services and license fees. Collaboration revenue includes revenue 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 for the years ended December 31, 2010, 2009 and 2008 (in thousands, except for percentages):

Revenues:	Years Ended December 31,			Increase (Decrease) from		Increase (Decrease) from	
	2010	2009	2008	2009 to 2010	%	2008 to 2009	%
Collaboration revenue	\$ 19,535	\$ 35,534	\$ 31,666	\$ (15,999)	(45)%	\$ 3,868	12%
Grant revenue	3,940	3,477	2,999	463	13%	478	16%
Services and license revenue	475	1,307	2,429	(832)	(64)%	(1,122)	(46)%
Total revenues	\$ 23,950	\$ 40,318	\$ 37,094	\$ (16,368)	(41)%	\$ 3,224	9%

Total revenues for the year ended December 31, 2010 decreased by \$16.4 million, or 41%, as compared to 2009 primarily due to the reduction in collaboration revenue following the termination of our collaboration with Merck. Collaboration revenue for the year ended December 31, 2010 included recognition of the \$10.0 million upfront payment received from AstraZeneca in 2006 following the recent amendment of our collaboration agreement, \$4.1 million of other revenue related to our collaboration with AstraZeneca, and a \$4.0 million payment from Merck in satisfaction of its obligations. Grant revenue for the year ended December 31, 2010 increased from the same period in 2009 primarily due to the increase in revenue recognized for the NIAID

**Table of Contents**

contract. Services and license revenue for the year ended December 31, 2010 decreased as compared to 2009 as a result of a decline in royalty revenue and manufacturing services from Rhein Biotech GmbH ( Rhein or Dynavax Europe ).

Total revenues for the year ended December 31, 2009 increased by \$3.2 million, or 9%, as compared to 2008 primarily resulting from higher collaboration revenue. Collaboration revenue for the year ended December 31, 2009 included recognition of \$28.5 million of the upfront payment from the Merck collaboration following its termination, and \$5.1 million of other revenue related to our collaboration with AstraZeneca. Grant revenue for the year ended December 31, 2009 increased from the same period in 2008 due primarily to revenues earned from the NIAID contract. Services and license revenue for the year ended December 31, 2009 decreased as compared to 2008 as a result of a decline in research and development services provided by Rhein.

**Research and Development**

Research and development expenses consist 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 percentages):

Research and Development:	Years Ended December 31,			Increase (Decrease) from 2009 to 2010		Increase (Decrease) from 2008 to 2009	
	2010	2009	2008	\$	%	\$	%
Compensation and related personnel costs	\$ 14,867	\$ 15,601	\$ 18,020	\$ (734)	(5)%	\$ (2,419)	(13)%
Outside services	31,372	14,985	18,477	16,387	109%	(3,492)	(19)%
Facility costs	6,809	6,983	6,871	(174)	(2)%	112	2%
Non-cash stock-based compensation	632	1,139	1,403	(507)	(45)%	(264)	(19)%
<b>Total research and development</b>	<b>\$ 53,680</b>	<b>\$ 38,708</b>	<b>\$ 44,771</b>	<b>\$ 14,972</b>	<b>39%</b>	<b>\$ (6,063)</b>	<b>(14)%</b>

Research and development expense for the year ended December 31, 2010 increased by \$15.0 million, or 39%, as compared to 2009. The increase in outside services during 2010 is primarily due to continued clinical and manufacturing activities associated with HEPLISAV. The increase in outside services expense was partially offset by a decrease in compensation and related personnel costs and stock-based compensation over the same period primarily due to the decline in employee headcount.

Research and development expenses for the year ended December 31, 2009 decreased by \$6.1 million, or 14%, as compared to 2008. The decrease in outside services during 2009 resulted from reduced clinical development costs for HEPLISAV during the period in which HEPLISAV was on clinical hold and the discontinuation of clinical development for the TOLAMBA ragweed allergy program. Compensation and related personnel costs decreased in 2009 due to a reduction in the number of employees engaged in research and development.

We expect research and development expenses in 2011 to be consistent with 2010.

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

General and administrative expenses consist 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 expenses (in thousands, except for percentages):

General and Administrative:	Years Ended December 31,			Increase (Decrease) from 2009 to 2010		Increase (Decrease) from 2008 to 2009	
	2010	2009	2008	\$	%	\$	%
Compensation and related personnel costs	\$ 6,318	\$ 5,886	\$ 6,810	\$ 432	7%	\$ (924)	(14)%
Outside services	4,207	4,033	4,209	174	4%	(176)	(4)%
Legal costs	3,622	3,003	1,696	619	21%	1,307	77%
Facility costs	971	927	946	29	3%	(19)	(2)%
Non-cash stock-based compensation	1,761	1,896	1,802	(135)	(7)%	94	5%
Total general and administrative	\$ 16,879	\$ 15,745	\$ 15,463	\$ 1,134	7%	\$ 282	2%

General and administrative expenses for the year ended December 31, 2010 increased by \$1.1 million, or 7%, compared to the same period in 2009. The increase is primarily due to an increase in legal costs related to patent activities, as well as personnel costs for travel and recruitment to support HEPLISAV development and other business efforts.

General and administrative expenses for the year ended December 31, 2009 increased by \$0.3 million, or 2%, compared to the same period in 2008. The increase is primarily due to an increase in legal costs related to patent activities, partially offset by a decrease in compensation and related personnel costs resulting from a reduction in the number of administrative employees providing organizational support.

We expect general and administrative expenses in 2011 to be consistent with 2010.

**Amortization of Intangible Assets**

Intangible assets consist primarily of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over five years from the date of acquisition. Amortization of intangible assets was \$1.0 million for each of the three years ended December 31, 2010, 2009 and 2008.

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

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency transactions, gains and losses on disposals of property and equipment and the change in fair value of financial assets and liabilities such as the warrants and contingent consideration liabilities assumed in connection with the acquisition of SDI on December 30, 2009. Interest expense includes amortization of deferred transaction costs and commitment fees related to the Deerfield Loan Agreement dated July 18, 2007 (the Loan Agreement) and accretion of the note payable issued to Holdings in connection with our acquisition of SDI. The following is a summary of our interest income, interest expense, other income (expense) and loan forgiveness (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2009 to 2010		Increase (Decrease) from 2008 to 2009	
	2010	2009	2008	\$	%	\$	%
Interest income	\$ 85	\$ 178	\$ 1,631	\$ (93)	(52)%	\$ (1,453)	(89)%
Interest expense	\$ (1,654)	\$ (124)	\$ (9,157)	\$ 1,530	1234%	\$ (9,033)	(99)%
Other income (expense)	\$ (8,150)	\$ (66)	\$ 110	\$ 8,084	12248%	\$ (176)	(160)%

Loan forgiveness	\$	\$	\$ 5,000	\$	\$ (5,000)	(100)%
------------------	----	----	----------	----	------------	--------

## **Table of Contents**

Interest income for the year ended December 31, 2010 decreased by \$0.1 million, or 52%, compared to the same period in 2009 due primarily to lower returns on our investment portfolio resulting from market conditions. Interest income for the year ended December 31, 2009 decreased by \$1.5 million, or 89%, compared to the same period in 2008 due primarily to lower investment balances and the decline in returns on our investment portfolio resulting from market conditions.

Interest expense for the year ended December 31, 2010 increased by \$1.5 million compared to the same period in 2009 due primarily to interest from the accretion of the note payable to Holdings. Interest expense for the year ended December 31, 2009 decreased by \$9.0 million, or 99%, compared to the same period in 2008 due primarily to the termination of the Loan Agreement with Deerfield in August 2008.

Other income (expense) for the year ended December 31, 2010 primarily includes the impact of the anti-dilution provision associated with the common stock and warrants issued to Symphony in April 2010, the warrant liability remeasured through June 30, 2010, which resulted in non-operating expense of \$11.0 million, partially offset by a gain of \$2.2 million for the change in fair value of the long-term contingent liability to Symphony. Following the expiration date of Symphony's anti-dilution protection of June 30, 2010, the value of the April 2010 Warrants were reclassified in stockholders' equity in the consolidated balance sheet. Additionally, in 2010 we received \$0.7 million in grants under The Patient Protection and Affordable Care Act of 2010, awarded to us to cover research and development costs from 2009 and 2010 for our qualified therapeutic discovery projects including HEPLISAV.

Loan forgiveness in 2008 represents a \$5.0 million portion of the loan from Deerfield that was forgiven upon termination of the loan agreement.

### ***Losses Attributable to Noncontrolling Interest in Symphony Dynamo, Inc.***

Pursuant to the agreements that we entered into with SDI (a VIE) in April 2006, the results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006. We have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated statements of operations through December 30, 2009, the date we acquired all the outstanding equity of SDI. For the fiscal years ended December 31, 2010, 2009 and 2008, the losses attributable to the noncontrolling interest were zero, \$4.2 million and \$5.7 million, respectively.

### ***Consideration Paid in Excess of Carrying Value of the Noncontrolling Interest in Symphony Dynamo, Inc.***

Upon closing of the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option, we recorded the acquisition as a capital transaction that did not affect our net loss. However, because the acquisition was accounted for as a capital transaction, the excess consideration transferred over the carrying value of the noncontrolling interest in SDI was treated as a deemed dividend for purposes of reporting net loss and net loss per share attributable to us, increasing net loss and net loss per share attributable to our common stockholders by \$19.7 million or \$0.76 per share for the year ended December 31, 2009.

## **Recent Accounting Pronouncements**

### ***Accounting Standards Update 2010-17***

In March 2010, the FASB reached a consensus on Accounting Standards Update (ASU) No. 2010-17, Milestone Method of Revenue Recognition, or ASU 2010-17. ASU 2010-17 provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under the consensus, entities can make an accounting policy election to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. The scope of this Issue is limited to

## **Table of Contents**

transactions involving research or development. This new guidance is effective for fiscal years beginning on or after June 15, 2010, and we will adopt it prospectively as of January 1, 2011 such that it will be applicable to revenue arrangements entered into or materially modified on or after that date. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

### ***Accounting Standards Update 2010-06***

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* or ASU 2010-06, which is included in the ASC Topic 820 (Fair Value Measurements and Disclosures). ASU 2010-06 requires new disclosures on the amount and reason for transfers in and out of Level 1 and 2 fair value measurements. ASU 2010-06 also requires disclosure of activities including purchases, sales, issuances, and settlements within the Level 3 fair value measurements and clarifies existing disclosure requirements on levels of disaggregation and disclosures about inputs and valuation techniques. We adopted ASU 2010-06 effective January 1, 2010. The adoption of ASU 2010-06 did not have a material impact on the consolidated financial statements of the Company.

### ***Accounting Standards Update 2009-13***

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* or ASU No. 2009-13. ASU No. 2009-13 amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services in order to treat deliverables in an arrangement as separate units of accounting and provides for separate revenue recognition based upon management's estimate of the relative selling price for each deliverable in an arrangement. This new guidance is effective for fiscal years beginning on or after June 15, 2010, and we will adopt it prospectively as of January 1, 2011 such that it will be applicable to revenue arrangements entered into or materially modified on or after that date. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

## **Liquidity and Capital Resources**

As of December 31, 2010, we had \$72.2 million in cash, cash equivalents and marketable securities. Our funds are currently invested in short-term money market funds, government agency securities and corporate obligations.

Cash used in operating activities during the year ended December 31, 2010 was \$51.4 million compared to \$33.6 million for the same period in 2009. The increase in cash usage compared to the prior year was due to our net loss and changes in working capital, particularly increased spending for HEPLISAV development. Cash used in operating activities during the year ended December 31, 2009 was \$33.6 million compared to \$17.0 million for the same period in 2008. The increase in cash usage over the prior year was due primarily to the decline in payments received from the collaboration with Merck, which was terminated in December 2008 and an increase in our net loss for 2009.

Cash used in investing activities during the year ended December 31, 2010 was \$50.5 million compared to cash provided of \$19.9 million for 2009. The change was primarily due to the purchase of marketable securities in 2010. Cash provided by investing activities during the year ended December 31, 2009 was \$19.9 million compared to \$30.1 million for the same period in 2008. The decrease in cash provided was primarily attributed to fewer proceeds from maturities of marketable securities.

## Table of Contents

Cash provided by financing activities during the year ended December 31, 2010 was \$87.6 million compared to \$22.1 million for the same period in 2009. The increase was primarily attributed to the completion of public offerings in April and November 2010, which resulted in aggregated net proceeds of \$87.4 million. Additionally, prior to the termination of our equity distribution agreement with Wedbush Morgan Securities ( Wedbush ) on September 14, 2010, we sold 900,860 shares of common stock for net proceeds of \$1.2 million during fiscal year 2010. Cash provided by financing activities during the year ended December 31, 2009 was \$22.1 million compared to \$1.4 million for the same period in 2008. Cash provided by financing activities primarily included gross proceeds of \$20.1 million from the acquisition of SDI and \$2.2 million from sales of our common stock under an equity distribution agreement entered into with Wedbush on August 17, 2009.

On September 20, 2010, we entered into the Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase an aggregate of \$30.0 million of shares of our common stock over the 25-month term of the Purchase Agreement. Under the Purchase Agreement, we agreed to pay Aspire Capital a commitment fee equal to 4% of \$30 million in consideration for Aspire Capital's obligation to purchase up to \$30 million of our common stock. We paid this commitment fee by issuance of 600,000 shares of our common stock valued at \$2.00 per share. Upon execution of the Purchase Agreement, we sold 1,000,000 shares of our common stock to Aspire Capital at a purchase price of \$2.00 per share, for an aggregate purchase price of \$2 million. In October 2010, we raised approximately \$1.3 million from the issuance of 750,000 shares of common stock under the Purchase Agreement. As of December 31, 2010, we could offer and sell from time to time to Aspire Capital up to an additional \$26.7 million in aggregate offering price of our common stock under the Purchase Agreement.

On November 2, 2010, we completed an underwritten public offering of 26,450,000 shares of our common stock including 3,450,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of \$1.70 per share. The net proceeds to us from this offering were \$42.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

We expect to continue to spend substantial funds in connection with development and manufacturing of our product candidates, particularly HEPLISAV; various human clinical trials for our product candidates; and protection of our intellectual property. In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise additional funds. This may occur through our Purchase Agreement with Aspire Capital, future public or private financings and/or strategic alliance and licensing arrangements. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

We currently estimate that we will have sufficient cash resources to meet our cash needs through the next twelve months based on cash and cash equivalents and marketable securities on hand at December 31, 2010, anticipated revenues from existing agreements and the funding available to us under the Purchase Agreement with Aspire Capital. We note that our independent registered public accounting firm has included in their audit opinion for the fiscal year ended December 31, 2010, a statement with respect to substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

**Table of Contents****Contractual Obligations**

The following summarizes our significant contractual obligations as of December 31, 2010 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	Payments due by Period			
		Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
Future minimum payments under our operating leases, excluding payments from a sublease agreement	\$ 15,992	\$ 2,023	\$ 5,587	\$ 3,806	\$ 4,576
Long-term note payable to Symphony Dynamo Holdings	15,000		15,000		
<b>Total</b>	<b>\$ 30,992</b>	<b>\$ 2,023</b>	<b>\$ 20,587</b>	<b>\$ 3,806</b>	<b>\$ 4,576</b>

We lease our facilities in Berkeley, California or the Berkeley Lease, and Düsseldorf, Germany (the Düsseldorf Lease) under operating leases that expire in September 2017 and March 2023, respectively. In October 2010, we amended our Berkeley Lease to reduce the Company's leased premises and extend the term of the lease through September 30, 2017. Commencing on the reduction effective date, which is no later than April 1, 2011, the monthly base rent for the Berkeley facility will be reduced proportionately by the reduction in square footage and is subject to scheduled escalation on an annual basis thereafter. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with the total remaining scheduled payments of \$10,600 due to us until February 2011. We have also entered into two sublease agreements under the Düsseldorf Lease for certain portion of the leased space with total remaining scheduled payments of \$0.2 million due to us through July 2013.

As part of the consideration we transferred to Holdings for the acquisition of SDI, we are obligated to make contingent cash payments equal to 50% of the first \$50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies. Using a discounted cash flow model, we estimated the fair value of the contingent liability to be \$0.8 million as of December 31, 2010.

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 December 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2010 and 2009. 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 December 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2010 and 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.



## **Table of Contents**

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2010, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 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 covered by patents and patent applications originating from the licensed technologies. Under the terms of our license agreements, we expected to pay approximately \$0.8 million through 2012 related to such fees and milestone payments to the Regents.

### ***Off-balance Sheet Arrangements***

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC 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 VIE and is included in our financial statements through December 30, 2009, the date we acquired all the outstanding equity in SDI. Our financing arrangement with SDI does not qualify as an off-balance sheet arrangement as defined by applicable SEC regulations.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### **Quantitative and Qualitative Disclosure 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. Our investment portfolio approach has been consistent for our recent fiscal years. 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.

*Foreign Currency Risk.* We have certain investments outside the United States 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 December 31, 2010 was \$0.7 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. To date, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

**Table of Contents**

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page No.</b>
<u>Report of Independent Registered Public Accounting Firm</u>	46
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	47
<u>Consolidated Statements of Operations</u>	48
<u>Consolidated Statements of Stockholders' Equity</u>	49
<u>Consolidated Statements of Cash Flows</u>	50
<u>Notes to Consolidated Financial Statements</u>	51

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dynavax Technologies Corporation at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, Dynavax Technologies Corporation's recurring losses from operations raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters also are described in Note 2. The 2010 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2011, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 11, 2011

**Table of Contents****DYNAVAX TECHNOLOGIES CORPORATION****CONSOLIDATED BALANCE SHEETS****(In thousands, except per share amounts)**

	December 31,	
	2010	2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,453	\$ 36,720
Marketable securities	49,701	
Accounts receivable	1,001	895
Prepaid expenses and other current assets	1,360	586
<b>Total current assets</b>	<b>74,515</b>	<b>38,201</b>
Property and equipment, net	6,404	7,997
Goodwill	2,312	2,312
Other intangible assets, net	299	1,279
Restricted cash	652	681
Other assets	67	
<b>Total assets</b>	<b>\$ 84,249</b>	<b>\$ 50,470</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,329	\$ 1,686
Accrued liabilities	10,943	7,507
Deferred revenues	1,429	2,718
Warrant liability to Symphony Dynamo Holdings LLC (Holdings)		2,567
<b>Total current liabilities</b>	<b>14,701</b>	<b>14,478</b>
Deferred revenues, noncurrent	5,655	17,083
Long-term note payable to Holdings	10,939	9,342
Long-term contingent liability to Holdings	843	3,040
Other long-term liabilities		151
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2010 and 2009		
Common stock: \$0.001 par value; 150,000 shares authorized at December 31, 2010 and 2009; 115,611 and 54,279 shares issued and outstanding at December 31, 2010 and 2009, respectively		
	116	54
Additional paid-in capital	369,686	266,127
Accumulated other comprehensive loss:		
Unrealized gain on marketable securities available-for-sale	(17)	
Cumulative translation adjustment	(729)	(168)
<b>Total accumulated other comprehensive loss</b>	<b>(746)</b>	<b>(168)</b>
Accumulated deficit	(316,945)	(259,637)
<b>Total stockholders' equity</b>	<b>52,111</b>	<b>6,376</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 84,249</b>	<b>\$ 50,470</b>

*See accompanying notes.*

**Table of Contents**

**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

	Years Ended December 31,		
	2010	2009	2008
<b>Revenues:</b>			
Collaboration revenue	\$ 19,535	\$ 35,534	\$ 31,666
Grant revenue	3,940	3,477	2,999
Service and license revenue	475	1,307	2,429
<b>Total revenues</b>	<b>23,950</b>	<b>40,318</b>	<b>37,094</b>
<b>Operating expenses:</b>			
Research and development	53,680	38,708	44,771
General and administrative	16,879	15,745	15,463
Amortization of intangible assets	980	980	980
<b>Total operating expenses</b>	<b>71,539</b>	<b>55,433</b>	<b>61,214</b>
<b>Loss from operations</b>	<b>(47,589)</b>	<b>(15,115)</b>	<b>(24,120)</b>
Interest income	85	178	1,631
Interest expense	(1,654)	(124)	(9,157)
Other income (expense)	(8,150)	(66)	110
Loan forgiveness			5,000
<b>Net loss</b>	<b>(57,308)</b>	<b>(15,127)</b>	<b>(26,536)</b>
Consideration paid in excess of carrying value of the noncontrolling interest in Symphony Dynamo, Inc. (SDI)		(19,671)	
Add: Losses attributable to noncontrolling interest in SDI		4,233	5,707
<b>Net loss attributable to Dynavax</b>	<b>\$ (57,308)</b>	<b>\$ (30,565)</b>	<b>\$ (20,829)</b>
<b>Basic and diluted net loss per share attributable to Dynavax common stockholders</b>	<b>\$ (0.69)</b>	<b>\$ (0.76)</b>	<b>\$ (0.52)</b>
<b>Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders</b>	<b>82,463</b>	<b>40,350</b>	<b>39,819</b>

*See accompanying notes.*

**Table of Contents****DYNAVAX TECHNOLOGIES CORPORATION****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

(In thousands)

	Common Stock		Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Total Dynavax Stockholders Equity	Noncontrolling Interest in SDI	Total Stockholders Equity
	Shares	Par Amount	Paid-In Capital					
Balances at December 31, 2007	39,765	\$ 40	\$ 258,266	\$ 398	\$ (227,914)	\$ 30,790	\$ 8,341	\$ 39,131
Exercise of stock options	2		5			5		5
Issuance of common stock under Employee Stock Purchase Plan	87		204			204		204
Modification of warrants in conjunction with Deerfield financing agreement			899			899		899
Stock compensation expense			3,205			3,205		3,205
Comprehensive loss:								
Change in unrealized gain on marketable securities				(89)		(89)		(89)
Cumulative translation adjustment				(663)		(663)		(663)
Net loss					(20,829)	(20,829)	(5,707)	(26,536)
Total comprehensive loss						(21,581)	(5,707)	(27,288)
Balances at December 31, 2008	39,854	40	262,579	(354)	(248,743)	13,522	2,634	16,156
Issuance of common stock upon financing	13,000	13	18,577			18,590		18,590
Issuance of common stock upon exercise of stock options and restricted stock awards	8		13			13		13
Issuance of common stock under Employee Stock Purchase Plan	136		72			72		72
Proceeds from issuance of common stock, net of fees	1,281	1	2,241			2,242		2,242
Modification of warrants in conjunction with Deerfield agreement			84			84		84
Reclassification of warrant liability issued in conjunction with the SDI transaction			(2,567)			(2,567)		(2,567)
Issuance of warrants in conjunction with SDI agreements			1,764			1,764		1,764
Excess consideration paid for the noncontrolling interest in SDI			(19,671)			(19,671)		(19,671)
Stock compensation expense			3,035			3,035		3,035
Dividends paid to SDI shareholders							(335)	(335)
Dividends paid to SDI shareholders							1,934	1,934
Comprehensive loss:								
Change in unrealized gain on marketable securities				(49)		(49)		(49)
Cumulative translation adjustment				235		235		235
Net loss					(10,894)	(10,894)	(4,233)	(15,127)
Total comprehensive loss						(10,708)	(4,233)	(14,941)
Balances at December 31, 2009	54,279	54	266,127	(168)	(259,637)	6,376		6,376
Issuance of common stock upon exercise of stock options and restricted stock awards	141	1	159			160		160
Issuance of common stock under Employee Stock Purchase Plan	121		72			72		72
Proceeds from issuances of common stock and warrants, net of fees	59,994	59	87,340			87,399		87,399

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Reclassification of the warrant liability to Holdings into equity and the impact of the anti-dilution provision associated with the common stock and warrants issued to Holdings	1,076	2	13,578		13,580	13,580
Stock compensation expense			2,410		2,410	2,410
Comprehensive loss:						
Change in unrealized gain on marketable securities				(17)	(17)	(17)
Cumulative translation adjustment				(561)	(561)	(561)
Net loss				(57,308)	(57,308)	(57,308)
Total comprehensive loss					(57,886)	(57,886)
Balances at December 31, 2010	115,611	\$ 116	\$ 369,686	\$ (746)	\$ (316,945)	\$ 52,111
						\$ 52,111

*See accompanying notes.*



**Table of Contents**

**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Years Ended December 31,		
	2010	2009	2008
<b>Operating activities</b>			
Net loss attributable to Dynavax	\$ (57,308)	\$ (30,565)	\$ (20,829)
Adjustments to reconcile net loss to net cash used in operating activities:			
Consideration paid in excess of carrying value of the noncontrolling interest in SDI		19,671	
Amount attributed to noncontrolling interest in SDI		(4,233)	(5,707)
Depreciation and amortization	1,415	1,857	1,850
Amortization of intangible assets	980	980	980
(Gain) loss on disposal of property and equipment	(36)	12	32
Accretion and amortization of marketable securities	367	4	(721)
Non-cash interest associated with long-term note payable to Holdings	1,597		
Fair value adjustment of the warrant and contingent liabilities to Holdings, including the impact of the anti-dilution provision associate with the common stock and warrants issued to Symphony	8,816		
Interest associated with Deerfield financing agreement		84	9,090
Loan forgiveness			(5,000)
Stock compensation expense	2,410	3,035	3,205
Changes in operating assets and liabilities:			
Accounts receivable	(106)	5,512	827
Prepaid expenses and other current assets	(774)	405	1,533
Restricted cash and other assets	(38)	(13)	(79)
Accounts payable	643	781	(3,513)
Accrued liabilities and other long term liabilities	3,381	762	(6,129)
Deferred revenues	(12,717)	(31,844)	7,426
Net cash used in operating activities	(51,370)	(33,552)	(17,035)
<b>Investing activities</b>			
Change in investments held by SDI		5,041	6,522
Purchases of marketable securities	(80,835)	(14,289)	(35,755)
Proceeds from maturities of marketable securities	30,750	29,500	59,401
Proceeds from sales of marketable securities			4,046
Purchases of property and equipment, net	(420)	(377)	(4,098)
Net cash provided by (used in) investing activities	(50,505)	19,875	30,116
<b>Financing activities</b>			
Cash acquired from the purchase of noncontrolling interest in SDI		19,732	
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	87,399	2,242	
Proceeds from exercise of stock options and restricted stock awards	160	13	5
Proceeds from employee stock purchase plan	72	72	204
Net cash provided by financing activities	87,631	22,059	1,392
Effect of exchange rate on cash and cash equivalents	(23)	235	(663)
Net (decrease) increase in cash and cash equivalents	(14,267)	8,617	13,810
Cash and cash equivalents at beginning of year	36,720	28,103	14,293
Cash and cash equivalents at end of year	\$ 22,453	\$ 36,720	\$ 28,103

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

**Supplemental disclosure of cash flow information**

Cash paid during the year for interest	\$	\$	\$ 885
Non-cash investing and financing activities:			
Shares issued to Aspire Capital in conjunction with purchase agreement	\$ 1,200	\$	\$
Note payable issued to Holdings from purchase option exercised under the SDI collaboration	\$	\$ 9,342	\$
Shares issued in conjunction with the SDI transaction	\$ 1,551	\$ 18,590	\$
Liability from program option exercised under the SDI collaboration	\$	\$ (15,000)	\$
Warrants issued in conjunction with the SDI transaction	\$ 6,638	\$ 1,764	\$
Loan forgiveness	\$	\$	\$ 5,000
Modification of warrants previously issued to Deerfield	\$	\$ 84	\$ 899
Disposal of fully depreciated property and equipment	\$ 42	\$ 1,215	\$

*See accompanying notes.*

---

**Table of Contents**

**DYNAVAX TECHNOLOGIES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization**

Dynavax Technologies Corporation ( Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine and hepatitis C and hepatitis B therapies; and preclinical programs partnered with GlaxoSmithKline ( GSK ) and AstraZeneca. 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. Our product candidates are based on the use of immunostimulatory and immunoregulatory sequences. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2001.

**Subsidiaries**

In December 2009, we completed the acquisition of Symphony Dynamo, Inc. ( SDI ), which became a wholly-owned subsidiary (see Note 8). In April 2006, we completed the acquisition of Rhein Biotech GmbH ( Rhein ), a wholly-owned subsidiary in Düsseldorf, Germany.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The consolidated financial statements include our accounts and those of our wholly-owned subsidiaries. Prior to December 30, 2009, Dynavax consolidated the financial results of SDI, as SDI was deemed a variable interest entity and we were deemed the primary beneficiary. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products. In fiscal years 2010, 2009 and 2008, 98%, 97% and 93% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Europe. As of December 31, 2010 and 2009, 41% and 43%, respectively, of our long-lived assets were located in the United States and the remaining assets were located in Europe. We have reclassified the prior year restricted cash balance from current to long-term in order to conform to the current year presentation. The reclassification had no impact on our overall financial position or results of operations.

**Liquidity and Financial Condition**

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2010, we had cash, cash equivalents and marketable securities of \$72.2 million, restricted cash of \$0.7 million and working capital of \$59.8 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents and marketable securities on hand at December 31, 2010, anticipated revenues from existing agreements and the funding available to us under the September 2010 Common Stock Purchase Agreement (the Purchase Agreement ) with Aspire Capital Fund, LLC ( Aspire Capital ).

In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise significant additional funds. This may occur through our Purchase Agreement with Aspire Capital, future public or private financings and/or strategic alliance and licensing arrangements. Sufficient additional funding may not

## **Table of Contents**

be available on acceptable terms, or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program or our other development programs while we seek strategic alternatives.

The accompanying financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

### **Use of Estimates**

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

### **Foreign Currency**

We consider the local currency to be the functional currency for our international subsidiary. Accordingly, assets and liabilities denominated in foreign currencies are translated into U.S. dollars using the exchange rate on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the year. Currency translation adjustments are charged or credited to accumulated other comprehensive income (loss) in the consolidated balance sheets. For the years ended December 31, 2010, 2009 and 2008, we reported a loss of \$0.7 million, a gain of \$0.2 million, and a loss of \$0.7 million, respectively. Gains and losses resulting from currency transactions are included in the consolidated statements of operations. We reported a \$0.1 million loss resulting from currency transactions in our consolidated statement of operations for the year ended December 31, 2010.

### **Cash, Cash Equivalents and Marketable 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.

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. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; 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 securities with unrealized gains and losses included in accumulated other comprehensive income (loss) 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 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.

## **Table of Contents**

To date, there have been no declines in fair value that have been identified as other than temporary.

### **Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that are subject to concentration of credit risk consist primarily of cash and cash equivalents, marketable securities, and accounts receivable. Our policy is to invest cash in institutional money market funds and marketable securities of U.S. government and corporate issuers with high credit quality in order to limit the amount of credit exposure. We currently maintain a 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. We have not experienced any losses on our cash and cash equivalents and marketable securities.

Trade accounts receivable are recorded at invoice value. We review our exposure to accounts receivable, including the potential for allowances based on management's judgment. We have not historically experienced any significant losses. We do not currently require collateral for any of our trade accounts receivable.

Our future products will require approval from the U.S. Food and Drug Administration and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals would have a material adverse impact on our business.

We have relied on a limited number of suppliers to produce ISS for clinical trials and a single contract manufacturer to produce our 1018 ISS for HEPLISAV. The loss of our current supplier could delay development or commercialization of our product candidates. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes.

We are subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, clinical development risk, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of products, product liability, the volatility of our stock price and the need to obtain additional financing.

### **Property and Equipment**

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. The assets held in our Berkeley facility have estimated useful lives of three years for computer equipment and furniture, and five years for laboratory equipment. The assets in our Düsseldorf, Germany facility have estimated useful lives of three years for computer equipment and thirteen years for furniture and laboratory equipment. Leasehold improvements in both facilities are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter. Repair and maintenance costs are charged to expense as incurred.

### **Impairment of Long-lived Assets**

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

significant changes in the strategy for our overall business;

significant underperformance relative to expected historical or projected future operating results;

significant changes in the manner of our use of acquired assets;

## **Table of Contents**

significant negative industry or economic trends;

significant decline in our stock price for a sustained period;

a current expectation that, more likely than not, a long lived asset (asset group) will be sold or otherwise disposed of significantly before the end of its previously estimated useful life; and

our market capitalization relative to net book value.

Recoverability is measured by comparison of the assets' carrying amounts to the future net undiscounted cash flows resulting from the use of the asset and its eventual disposition. If these assets are considered impaired, the impairment recognized is measured by the amount by which the carrying value of the assets exceed the projected discounted future net cash flows associated with the assets. For the years ended December 31, 2010, 2009 and 2008, we recognized no impairment charge as it relates to our long-lived assets.

## **Revenue Recognition**

Our revenues are derived from collaborative and service agreements as well as grants. Collaborative agreements may include upfront license payments, cost reimbursement for the performance of research and development, milestone payments, contract manufacturing services, and royalty fees. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under established accounting guidance. The different elements of the revenue arrangement are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. For agreements which do not meet the criteria of separate units of accounting, the total consideration received is grouped as one unit and the applicable revenue recognition methodology is applied to the single unit. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where we have continuing performance obligations is deferred and recognized as performance occurs. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Revenue from milestones that are contingent upon the achievement of substantive at-risk performance criteria is recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

## **Table of Contents**

### **Research and Development Expenses and Accruals**

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services, and non-cash stock-based compensation. Research and development costs are expensed as incurred. For agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities entered into prior to January 1, 2008, costs were expensed upon the earlier of when non-refundable amounts were due or as services were performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements entered into after January 1, 2008 are capitalized and expensed as the related goods are delivered or services are performed.

Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial or similar conditions. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties.

### **Goodwill**

Goodwill is recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the acquisition method of accounting. The ongoing evaluation for impairment of goodwill requires significant management estimates and judgment. We determined that we have only one operating segment and there are no components of that operating segment that are deemed to be reporting units. Since we are one reporting unit, we have allocated goodwill to that one reporting unit based on the relative fair value of the reporting unit. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired.

### **Consolidation of Variable Interest Entities**

Arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities ( VIEs ). An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

We have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Prior to the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option on December 30, 2009, our consolidated financial statements include the accounts of SDI, a VIE, of which we were the primary beneficiary (refer to Note 8 below).

## **Table of Contents**

### **Stock-Based Compensation**

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option's vesting period and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level and non-executive level employees were grouped and considered separately for valuation purposes. In 2008, based on employee termination data we adjusted the expected life of the options for both groups of employees to four years, which remained consistent for fiscal years ended December 31, 2009 and 2010. Expected volatility is based on historical volatility of our stock and comparable peer data over the life of the options granted to executive and non-executive level employees.

### **Income Taxes**

We account for income taxes using the liability method under ASC 740, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, we must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. We have provided a full valuation allowance on our deferred tax assets because we believe it is more likely than not that our deferred tax assets will not be realized. We evaluate the realizability of our deferred tax assets on a quarterly basis. Currently, there is no provision for income taxes as we have incurred losses to date.

We have no unrecognized tax benefits as of December 31, 2010, including no accrued amounts for interest and penalties. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2011. Our policy will be to recognize interest and penalties related to income taxes, if any, as a component of general and administrative expense. We are subject to income tax examinations for U.S. federal and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively.

### **Recent Accounting Pronouncements**

#### *Accounting Standards Update 2010-17*

In March 2010, the FASB reached a consensus on Accounting Standards Update (ASU) No. 2010-17, *Milestone Method of Revenue Recognition* or ASU 2010-17. ASU 2010-17 provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under the consensus, entities can make an accounting policy election to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. The scope of this issue is limited to transactions involving research or development. This new guidance is effective for fiscal years beginning on or after June 15, 2010, and we will adopt it prospectively as of January 1, 2011 such that it will be applicable to revenue arrangements entered into or materially modified after that date. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

#### *Accounting Standards Update 2010-06*

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements* or ASU 2010-06, which is included in the ASC Topic 820 (Fair Value Measurements and Disclosures). ASU 2010-06 requires new disclosures on the amount and reason for transfers in and out of Level 1



## **Table of Contents**

and 2 fair value measurements. ASU 2010-06 also requires disclosure of activities including purchases, sales, issuances, and settlements within the Level 3 fair value measurements and clarifies existing disclosure requirements on levels of disaggregation and disclosures about inputs and valuation techniques. We adopted ASU 2010-06 effective January 1, 2010. The adoption of ASU 2010-06 did not have a material impact on the consolidated financial statements of the Company.

### ***Accounting Standards Update 2009-13***

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* or ASU No. 2009-13. ASU No. 2009-13 amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services in order to treat deliverables in an arrangement as separate units of accounting and provides for separate revenue recognition based upon management's estimate of the relative selling price for each deliverable in an arrangement. This new guidance is effective for fiscal years beginning on or after June 15, 2010, and we will adopt it prospectively as of January 1, 2011 such that it will be applicable to revenue arrangements entered into or materially modified on or after that date. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

### **3. Fair Value Measurements**

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as 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 under ASC 820 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

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.

**Table of Contents****Fair Value on a Recurring Basis**

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and liabilities measured at fair value on a recurring basis as of December 31, 2010 and 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
<b>December 31, 2010</b>				
Assets:				
Money market funds	\$ 18,980	\$	\$	\$ 18,980
U.S. government agency securities		49,039		49,039
Corporate debt securities		1,764		1,764
Total assets	\$ 18,980	\$ 50,803	\$	\$ 69,783
Liabilities:				
Long-term contingent consideration liability to Holdings	\$	\$	\$ 843	\$ 843
Total liabilities	\$	\$	\$ 843	\$ 843

	Level 1	Level 2	Level 3	Total
<b>December 31, 2009</b>				
Assets:				
Money market funds	\$ 33,788	\$	\$	\$ 33,788
Total assets	\$ 33,788	\$	\$	\$ 33,788
Liabilities:				
Warrant liability to Holdings	\$	\$	\$ 2,567	\$ 2,567
Long-term contingent consideration liability to Holdings			3,040	3,040
Total liabilities	\$	\$	\$ 5,607	\$ 5,607

**Assets**

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Marketable securities are primarily comprised of U.S. Government sponsored and corporate debt securities which are measured at fair value using Level 2 inputs. The company reviews trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, the company uses market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

When determining if there are any other-than-temporary impairments on its investments, we evaluate: (i) whether the investment has been in a continuous realized loss position for over 12 months, (ii) the duration to maturity of our investments, (iii) our intention to hold the investments to maturity and if it is not more likely than not that the Company will be required to sell the investment before recovery of the amortized cost bases, (iv) the credit rating of each investment, and (v) the type of investments made. Through December 31, 2010, we have not recognized any other-than-temporary losses on our investments.

**Liabilities**

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

In connection with the exercise of the Company's purchase of all of the outstanding equity of SDI on December 30, 2009, we issued warrants to Holdings that were subject to certain anti-dilution protection in the

**Table of Contents**

event that we issued other equity securities within six months from December 30, 2009. Due to this adjustment provision, the warrants did not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock and therefore were recorded as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. This fair value measurement was based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect our assumptions in measuring fair value. In connection with an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Holdings received warrants to purchase 7,038,210 shares of common stock (April 2010 Warrants). The warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The incremental fair value of the April 2010 Warrants was remeasured at June 30, 2010 and resulted in an increase of \$9.5 million to the warrant liability, which was reported as a other expense in the consolidated statement of operations. Following the expiration of Symphony's anti-dilution protection on June 30, 2010, the value of the April 2010 Warrants of \$12.1 million was reclassified into stockholders' equity in the consolidated balance sheet.

The following table represents a reconciliation of the change in the fair value measurement of the warrant liability for the fiscal year ended December 31, 2010 (in thousands):

<b>Warrant Liability to Holdings</b>	<b>Amount</b>
Acquisition date fair value measurement at December 30, 2009	\$ 2,567
Adjustment to fair value measurement	9,462
Reclassification of warrant liability into equity	(12,029)
Balance as of December 31, 2010	\$

The original warrants and the April 2010 Warrants were valued and their related assumptions under the Black-Scholes option valuation model are as follows (in thousands, except for Black-Scholes assumptions):

<b>Warrant Liability Measurement Date:</b>	<b>Black-Scholes Assumptions</b>				<b>Exercise Price per Share</b>	<b>Assigned Value using Black-Scholes</b>
	<b>Risk-Free Interest Rate</b>	<b>Expected Life (in years)</b>	<b>Volatility</b>			
December 30, 2009	2.6%	5.0	1.5		\$ 1.94	\$ 2,567
March 31, 2010	2.6%	4.8	1.5		\$ 1.94	\$ 2,315
April 16, 2010	2.5%	4.7	1.5		\$ 1.94	\$ 2,579
June 30, 2010	1.8%	4.8	1.5		\$ 1.50	\$ 12,029

We are obligated to make future contingent cash payments to the former Holdings shareholders related to certain payments received by us, if any, from future partnering agreements pertaining to our hepatitis C and cancer therapy programs (see Note 8). We estimated the fair value of this contingent liability using a discounted cash flow model. The discounted cash flow model was derived from management's assumptions regarding the timing, amounts, and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at 16% and 18% rates for the fiscal years ended December 31, 2010 and 2009, respectively.

Changes in the fair value of the contingent consideration liability are recognized in Other income (expense) in the statement of operations in the period of the change. Certain events including, but not limited to, the timing and terms of any strategic partnership agreement of the hepatitis C therapy program could have a material impact on the fair value of the contingent consideration liability, and as a result, the Company's results of operations and financial position. During the fiscal year ended December 31, 2010, we reduced the assumed probability of our receipt of upfront and milestone payments from a potential partnership and extended the timing of when these

**Table of Contents**

expected receipts would occur. In addition, based on our assumptions regarding the Company's beta and risk free interest rate used in the discounted cash flow model and the timing of the expected cash receipts, the change in fair value of the contingent consideration liability resulted in other income of \$2.2 million for the fiscal year ended December 31, 2010. This fair value measurement was based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect our assumptions in measuring fair value.

The following table represents a reconciliation of the change in the fair value measurement of the contingent liability for the fiscal year ended December 31, 2010 (in thousands):

<b>Long-term Contingent Liability to Holdings:</b>	<b>Amount</b>
Acquisition date fair value measurement at December 30, 2009	\$ 3,040
Adjustment to fair value measurement	(2,197)
Balance as of December 31, 2010	\$ 843

**4. Available-for-Sale Securities**

The following is a summary of available-for-sale securities included in cash and cash equivalents and marketable securities as of December 31, 2010 and 2009 (in thousands):

	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>December 31, 2010:</b>				
Certificates of deposit and money market funds	\$ 19,797	\$	\$	\$ 19,797
U.S. Government agency securities	49,056		(17)	49,039
Corporate debt securities	1,764			1,764
Total	\$ 70,617	\$	\$ (17)	\$ 70,600

**December 31, 2009:**

Certificates of deposit and money market funds	\$ 34,634	\$	\$	\$ 34,634
--	-----------	----	----	-----------

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2010, 2009 and 2008. As of December 31, 2010, 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.

**5. Property and Equipment**

Property and equipment as of December 31, 2010 and 2009 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Laboratory equipment	\$ 14,173	\$ 14,937
Computer equipment	1,341	1,331
Furniture and fixtures	1,518	1,581
Leasehold improvements	3,872	3,734
	20,904	21,583
Less accumulated depreciation and amortization	(14,500)	(13,586)

Total	\$ 6,404	\$ 7,997
-------	----------	----------

Depreciation and amortization expense on property and equipment was \$1.4 million, \$1.9 million and \$1.9 million for the years ended December 31, 2010, 2009 and 2008, respectively.

**Table of Contents****6. Intangible Assets**

Intangible assets consist primarily of manufacturing process and customer relationships. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a process we use to make 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 December 31, 2010 and December 31, 2009 (in thousands):

	Estimated Useful Life (In years)	December 31, 2010			December 31, 2009		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
<b>Intangible Assets:</b>							
Manufacturing process	5	\$ 3,670	\$ (3,446)	\$ 224	\$ 3,670	\$ (2,712)	\$ 958
Customer relationships	5	1,230	(1,155)	75	1,230	(909)	321
Total		\$ 4,900	\$ (4,601)	\$ 299	\$ 4,900	\$ (3,621)	\$ 1,279

The estimated future amortization expense of purchased intangible assets is \$0.3 million through 2011.

**7. Current Accrued Liabilities**

Current accrued liabilities as of December 31, 2010 and 2009 consist of the following (in thousands):

	December 31,	
	2010	2009
Payroll and related expenses	\$ 2,485	\$ 2,521
Legal expenses	596	1,140
Third party research and development expense	6,130	2,155
Deferred Rent	784	860
Other accrued liabilities	948	831
Total	\$ 10,943	\$ 7,507

**8. Symphony Dynamo, Inc.**

On April 18, 2006, we, Symphony Capital Partners, L.P. and certain of its affiliates (together, "Symphony") and Holdings entered into a transaction involving a series of related agreements providing for the advancement of certain of our immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the "Programs"). Pursuant to these agreements, Symphony formed SDI and invested \$50 million to fund the Programs, and we licensed to Holdings our intellectual property rights related to the Programs, which were assigned to SDI. As a result of these agreements, Symphony owned 100% of the equity of Holdings, which owned 100% of the equity of SDI.

In connection with the transaction described above, Holdings granted to us an exclusive purchase option that gave us the right, but not the obligation, to acquire the outstanding equity securities of SDI, which would result in our reacquisition of the intellectual property rights that we licensed to Holdings (the "Original Purchase Option"). In exchange for the Original Purchase Option, we granted Holdings five-year warrants to purchase up to 2,000,000 shares of our common stock at an exercise price of \$7.32 per share pursuant to a warrant purchase agreement (the "Original Warrants"), and granted certain registration rights to Holdings pursuant to a registration rights agreement. We also received an exclusive option to purchase either the hepatitis B or hepatitis C therapy program (the "Program Option") during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program. We remained primarily responsible for the development of the cancer and hepatitis C therapy programs in accordance with a development plan and related development budgets that we agreed to with Holdings.





## **Table of Contents**

A variable interest entity, or VIE, is (i) an entity that has equity that is insufficient to permit the entity to finance its activities without additional subordinated financial support, or (ii) an entity that has equity investors that cannot make significant decisions about the entity's operations or that do not absorb their proportionate share of the expected losses or do not receive the expected residual returns of the entity. A VIE is required to be consolidated by the party that is deemed to be the primary beneficiary, which is the party that has exposure to a majority of the potential variability in the VIE's outcomes. Significant management judgment is required in the determination of an entity being considered a VIE.

Parties are deemed to be de facto agents if they cannot sell, transfer, or encumber their interests without the prior approval of an enterprise. Symphony is considered to be a de facto agent of the Company pursuant to this provision, and because we and Symphony as a related party group absorb a majority of SDI's variability, we evaluated whether we are most closely associated with SDI. We concluded that we were most closely associated with SDI and should consolidate SDI because (1) we originally developed the technology that was assigned to SDI, (2) we continued to oversee and monitor the Development Programs, (3) our employees continued to perform substantially all of the development work, (4) we significantly influenced the design of the responsibilities and management structure of SDI, (5) SDI's operations were substantially similar to our activities, and (6) through the Purchase Option, we had the ability to participate in the benefits of a successful development effort.

Prior to the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option on December 30, 2009, as described below, we consolidated the financial position and results of operations of SDI. Net losses incurred by SDI and charged to the noncontrolling interest were \$4.2 million and \$5.7 million for the fiscal years ended December 31, 2009 and 2008, respectively. We did not consolidate Holdings because we believed our variable interest, the Purchase Option, was on the stock of SDI. We believed SDI was a VIE because we had the Purchase Option to acquire its outstanding voting stock at prices that were fixed upon entry into the arrangement, with the specific price based upon the date the option is exercised. The fixed nature of the Purchase Option price limits Symphony's returns, as the investor in SDI.

Symphony was required to absorb the development risk for its equity investment in SDI. Symphony's equity investment in SDI was classified as a noncontrolling interest in the consolidated balance sheet. The noncontrolling interest held by Symphony was reduced by the \$5.6 million fair value of the warrants it received and \$2.6 million of fees we immediately paid to Symphony upon the transaction's closing because the total consideration provided by us to Symphony effectively reduces Symphony's at-risk equity investment in SDI. While we performed the research and development on behalf of SDI, our development risk was limited to the consideration we provided to Symphony (the warrants and fees). We exercised the Program Option in April 2007, which resulted in the recognition of a \$15.0 million liability to Symphony. The noncontrolling interest was further reduced for this obligation as it would have been paid to Symphony at the expiration of the SDI collaboration in 2011 if we did not exercise the Purchase Option, or would be included as part of the applicable purchase price upon exercise of the Purchase Option.

In December 2007, the FASB issued new guidance that required: (i) noncontrolling interests in subsidiaries be reported as a component of stockholders' equity in the consolidated balance sheet, (ii) noncontrolling interests continue to be attributed its share of losses even if that attribution results in a deficit noncontrolling interest balance, (iii) that earnings or losses attributed to the noncontrolling interests be reported as part of consolidated earnings and not as a separate component of income or expense, and (iv) disclosure of the attribution of consolidated earnings to the controlling and noncontrolling interests on the face of the consolidated statement of operations. On January 1, 2009, we adopted these provisions. Had the previous requirements been applied, the consolidated net loss attributable to our common stockholders would have increased by \$1.9 million and the loss per share attributable to our common stockholders would have increased by \$0.05, during the year ended December 31, 2009.

In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the Original Purchase Option. We completed the acquisition of all of the outstanding equity of SDI on

---

**Table of Contents**

December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to Symphony and certain of its co-investors: (i) 13,000,000 shares of common stock (the Shares); (ii) 5-year warrants to purchase 2,000,000 shares of common stock with an exercise price of \$1.94 per share (the Warrants); and (iii) a note in the principal amount of \$15 million, due December 31, 2012, payable in cash, our common stock or a combination thereof at our discretion, which obligation was previously payable solely in cash on April 18, 2011. In addition, we agreed to contingent cash payments from us equal to 50% of the first \$50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies originally licensed to SDI. The Original Warrants held by Symphony were cancelled as part of this transaction.

We recorded the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option as a return of equity to the noncontrolling interest. The acquisition was accounted for as a capital transaction that did not affect our consolidated net loss. However, because the acquisition was accounted for as a capital transaction, the consideration paid in excess of the carrying value of the noncontrolling interest in SDI is treated as a deemed dividend for purposes of reporting net loss and earnings per share, increasing net loss and net loss per share attributable to us for the year ended December 31, 2009. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

The fair value of our common stock issued to the Symphony investors was based on the closing sales price of our common stock on the NASDAQ Capital Market on December 30, 2009, the date the transaction was completed. The estimated fair values of the warrants transferred were calculated using the Black-Scholes valuation model.

We estimated the fair value of the non-interest bearing note payable to Holdings using a net present value model using a discount rate of 17%. Imputed interest will be recorded as interest expense over the term of the loan. The principal amount of \$15 million is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. If we elect to pay the note in shares of our common stock, the number of shares issued will be determined by our stock price at the date of payment.

We estimated the fair value of the contingent consideration liability for potential future payments using a discounted cash flow model. The discounted cash flow model was derived from management's assumptions regarding the timing, amounts, and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at a 16% rate.

Changes in the fair value of the acquisition-related contingent consideration liability subsequent to the December 30, 2009 acquisition date are recognized in other income and expense on our consolidated statement of operations in the period of the change. Certain events including, but not limited to the timing and terms of a strategic partnership, and the commercial success of the programs could have a material impact on the fair value of the contingent liability, and as a result, our results of operations.

The Shares and Warrants were subject to certain anti-dilution protection in the event that we issued other equity securities within six months from December 30, 2009. Due to this adjustment provision, the Warrants did not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock and therefore were recorded as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. As a result of an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Symphony received an additional 1,076,420 shares of common stock (April 2010 Shares) and warrants to purchase 7,038,210 shares of common stock (April 2010 Warrants) having the same terms as the warrants sold in the offering, which have an exercise price of \$1.50 per share and a term of five years. The Warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The fair value of the April 2010 Shares and incremental fair value of the April 2010 Warrants provided to Symphony, as measured upon issuance and remeasured at June 30, 2010, resulted in non-operating expense of

**Table of Contents**

\$11.1 million in the second quarter of 2010. This also resulted in an increase of \$9.5 million to the warrant liability and an increase of \$1.6 million to additional paid in capital as of June 30, 2010. Following the expiration date of Symphony's anti-dilution protection on July 1, 2010, the value of the April 2010 Warrants of \$12.0 million was reclassified in stockholders' equity in the consolidated balance sheet.

**9. Financing Agreements**

On November 2, 2010, we completed an underwritten public offering of 26,450,000 shares of our common stock including 3,450,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of \$1.70 per share. The net proceeds to us from this offering were \$42.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

On September 20, 2010, we entered into the Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of shares of Dynavax common stock over the 25-month term of the Purchase Agreement. Under the Purchase Agreement, we agreed to pay Aspire Capital a commitment fee equal to 4% of \$30 million in consideration for Aspire Capital's obligation to purchase up to \$30 million of Dynavax common stock. We paid this commitment fee of \$1.2 million by issuance of 600,000 shares of our common stock which were recorded as a cost of raising capital and netted against the gross proceeds. Upon execution of the Purchase Agreement, we sold 1,000,000 shares of common stock to Aspire Capital at a purchase price of \$2.00 per share, for an aggregate purchase price of \$2.0 million.

Pursuant to the Purchase Agreement, on any business day on which the closing sale price of our common stock exceeds \$1.00, over the 25-month term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice directing Aspire Capital to purchase up to 150,000 Purchase Shares per business day (defined in the Purchase Agreement as any day on which the principal market is open for trading including any day on which the principal market is open for trading for a period of time less than the customary time). We and Aspire Capital may mutually agree to increase the number of shares that may be sold per business day to as much as an additional 1,000,000 Purchase Shares per business day. The purchase price per Purchase Share is the lower of (i) the lowest sale price for the common stock on the date of sale or (ii) the arithmetic average of the three lowest closing sale prices for the common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date of those securities. During the year ended December 31, 2010, we sold through Aspire Capital an aggregate of 2,350,000 shares of common stock for net proceeds of \$3.2 million after deducting offering expenses. As of December 31, 2010, we could offer and sell from time to time through Aspire Capital up to an additional \$26.7 million in aggregate offering proceeds of our common stock under the Purchase Agreement.

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of \$41.1 million, after deducting the underwriting discount and offering expenses of approximately \$3.0 million, from the sale of 30,293,000 units at a per unit price of \$1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of \$1.50 per share, and is exercisable for a period of five years from the date of issuance. From this offering, warrants to purchase an aggregate of 15,145,669 shares of our common stock were outstanding as of December 31, 2010.

On August 17, 2009, we entered into an equity distribution agreement with Wedbush Morgan Securities, Inc. (Wedbush) pursuant to which we could 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 fiscal year ended December 31, 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. On September 14, 2010, the Company terminated the agreement with Wedbush. Prior to the termination of the agreement on September 14, 2010, during the year ended December 31, 2010 we sold 900,860 shares of common stock under the agreement with Wedbush as our sales agent for net proceeds of \$1.2 million.

**Table of Contents**

On August 26, 2008, we 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 us 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 our allergy franchise. Repayment of a portion of the loans to Deerfield was contingent upon the positive outcome of studies related to TOLAMBA , our product candidate for the treatment of ragweed allergy. If the TOLAMBA program was discontinued, we 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	Shares Issued	Risk-Free Interest Rate	Expected Life (in years)	Black-Scholes Assumptions		Assigned Value using Black-Scholes
				Volatility	Exercise Price per Share	
July 18, 2007	1,250	4.9%	5.5	0.7	\$ 5.13	\$ 3,350
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 \$9.0 million of deferred transaction cost into interest expense in the year ended December 31, 2008.

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 for the 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 for the 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:

Warrant Issuance Date	Shares Issued (in thousands)	Expiration Date	Exercise Price per Share
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
Total	3,550		

**Table of Contents**

- (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 volume weighted average price 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 years ended December 31, 2009 and 2008, respectively, due to these modifications. There were no amendments or additional contractual obligations during the year ended December 31, 2010. Additionally, there were no exercises of warrants during the years ended December 31, 2010 and 2009.

**10. 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 2017 and March 2023, respectively. In October 2010, we amended our Berkeley Lease to reduce our leased premises and extended the term of the lease through September 30, 2017. Commencing on the reduction effective date, which is no later than April 1, 2011, the monthly base rent for the Berkeley facility will be reduced proportionately by the reduction in square footage and is subject to scheduled escalation on an annual basis thereafter. 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. Total net rent expense related to our operating leases for the years ended December 31, 2010, 2009 and 2008, was \$2.6 million, \$2.5 million and \$2.5 million, respectively. Deferred rent was \$0.8 million and \$0.9 million as of December 31, 2010 and 2009, respectively.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with the remaining scheduled payments to us totaling \$10,600 until February 2011. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2010, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2011	\$ 2,023
2012	1,860
2013	1,882
2014	1,845
Thereafter	8,382
<b>Total</b>	<b>\$ 15,992</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 December 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2010 and 2009. 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.

---

## **Table of Contents**

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 December 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2010 and 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 December 31, 2010, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 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.

### **11. Collaborative Research, Development, and License Agreements**

#### **GlaxoSmithKline**

In December 2008, we entered into a worldwide strategic alliance with 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 milestone payments. 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 years ended December 31, 2010, 2009 and 2008, we recognized revenue of \$1.4 million, \$1.4 million and \$60 thousand, 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. Such agreement was extended through July 2010. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. AstraZeneca has the right to sublicense its rights upon our prior consent. We have the option to co-promote in the United States products arising from the collaboration, if any. We received an upfront payment of \$10 million, and are eligible to receive research funding, preclinical milestone payments, and potential future development milestones payments. Upon commercialization, we are also eligible to receive royalties based on product sales, if any.

In September 2008, we received a \$4.5 million milestone payment from AstraZeneca for the nomination of a candidate drug. Revenue from milestones received during the development plan is deferred and recognized

**Table of Contents**

ratably over our estimated performance period under the collaboration agreement. Revenue from the upfront payment had been deferred until certain contractual obligations were amended in September 2010. In September 2010, we amended our research collaboration and license agreement with AstraZeneca to amend certain indemnification obligations which allowed for the \$10 million upfront payment to be fully recognized as collaboration revenue in the third quarter of 2010. Revenue from the milestone payment received was deferred and recognized ratably over the estimated performance period of the collaboration agreement. For the years ended December 31, 2010, 2009 and 2008, we recognized revenue of \$0.8 million, \$1.7 million and \$2.0 million, respectively, related to the milestone for the nomination of a candidate drug. Revenue resulting from the performance of research services amounted to \$3.3 million, \$3.4 million and \$3.2 million for the years ended December 31, 2010, 2009, and 2008, respectively.

**National Institutes of Health and Other Funding**

In July 2010, we were awarded a \$0.6 million grant from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus (HPV). For the year ended December 31, 2010 we recognized revenue of approximately \$0.2 million related to expenses incurred.

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 NIH's 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 our program under Contract No. HHSN272200800038C. For the years ended December 31, 2010, 2009 and 2008, we recognized revenue related to this program of approximately \$3.2 million, \$1.6 million and \$0.2 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 years ended December 31, 2010, 2009 and 2008, we recognized revenue related to this program of approximately \$0.2 million, \$0.9 million and \$0.4 million, respectively.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants were 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 years ended December 31, 2010, 2009 and 2008, we recognized revenue related to these awards of zero, \$3.5 million and \$3.0 million, respectively.

**Merck & Co., Inc. ( Merck )**

In October 2007, we entered into a global license and development collaboration agreement and a related manufacturing agreement with Merck to jointly develop HEPLISAV, our 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 us. As a result of Merck's termination, we accelerated the applicable performance period over which we ratably recognized revenue from the upfront fee through the effective date of termination, which was in June 2009. For the years ended December 31, 2010, 2009, and 2008, we recognized revenue of zero, \$28.5 million, and \$5.0 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

**Table of Contents**

agreement totaled zero, \$0.3 million, and \$20.2 million for the years ended December 31, 2010, 2009 and 2008, respectively. Additionally, in March 2010, Merck agreed to make a \$4.0 million payment to us in satisfaction of its obligations for the wind down period following Merck's written notice of termination, which was recorded as collaboration revenue upon receipt.

**12. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to us 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 us 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, 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.

	Years Ended December 31,		
	2010	2009	2008
<b>Basic and diluted net loss per share (in thousands, except per share amounts):</b>			
Numerator:			
Net loss attributable to Dynavax	\$ (57,308)	\$ (30,565)	\$ (20,829)
Denominator for basic and diluted net loss per share attributable to Dynavax common stockholders:			
Weighted-average common shares outstanding	82,463	40,350	39,819
Basic and diluted net loss per share attributable to Dynavax common stockholders	\$ (0.69)	\$ (0.76)	\$ (0.52)

	December 31,		
	2010	2009	2008
<b>Outstanding securities not included in diluted net loss per share calculation (in thousands):</b>			
Options to purchase common stock	7,288	5,561	5,173
Warrants	25,734	5,550	5,550
	33,022	11,111	10,723

**13. Stockholders' Equity****Stock Plans**

As of December 31, 2010, we had three stock-based compensation plans: the 1997 Equity Incentive Plan; the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; the 2004 Employee Stock Purchase Plan, and the 2010 Employment Inducement Award Plan.

In January 1997, we adopted the 1997 Equity Incentive Plan (the "1997 Plan"). The 1997 Plan provides for the granting of stock options to employees and non-employees of the Company. Options granted under the 1997 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted to employees, including directors who are also considered employees. NSOs may be granted to employees and non-employees. Options under the 1997 Plan may be granted for periods of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors, provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (ii) the exercise price of an ISO granted to a 10% stockholder



**Table of Contents**

shall not be less than 110% of the estimated fair value of the shares on the date of grant. The options are exercisable immediately and generally vest over a four-year period (generally 25% after one year and in monthly ratable increments thereafter) for stock options issued to employees, directors and scientific advisors, and quarterly vesting over a four-year period or immediate vesting for stock options issued all other non-employees. All unvested shares issued under the 1997 Plan are subject to repurchase rights by the Company under such conditions as agreed to by the Company and the optionee. The 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.

In January 2004, the Board of Directors and stockholders adopted the 2004 Stock Incentive Plan (the 2004 Plan ) which became effective on February 11, 2004. Subsequently, we discontinued granting stock options under the 1997 Plan. The exercise price of all incentive stock options granted under the 2004 Plan is at least equal to 100% of the fair market value of the common stock on the date of grant. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of the Company's stock or the stock of any parent or subsidiary of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value on the grant date and the maximum term of these incentive stock options must not exceed five years. The maximum of an incentive stock option granted to any other participant must not exceed ten years. 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.

In January 2010, the Company's Board of Directors adopted a 2010 Employment Inducement Award Plan (the Inducement Plan ) to induce qualified individuals to join Dynavax. This Inducement Plan provides for the issuance of up to 1,500,000 shares of Dynavax Common Stock and became effective on January 8, 2010. Stockholder approval of the Inducement Plan is not required under NASDAQ Marketplace Rule 5635(c)(4).

Activity under our stock plans is set forth below:

	<b>Options and Awards</b>		
	<b>Available for Grant</b>	<b>Options Outstanding</b>	<b>Weighted-Average Price Per Share</b>
Balance at December 31, 2009	658,909	5,276,055	\$ 3.94
2004 Plan options authorized	400,000		
Inducement Plan options authorized	1,500,000		
2004 Plan options granted	(1,618,494)	1,618,494	\$ 1.67
Inducement Plan options granted	(1,080,500)	1,080,500	\$ 1.61
2004 Plan restricted stock units (RSUs) granted	(150,000)		
2004 Plan options exercised		(103,119)	1.01
1997 Plan options exercised		(36,000)	\$ 1.50
<b>Options cancelled:</b>			
2004 Plan options forfeited (unvested)	368,479	(368,479)	\$ 3.26
Inducement Plan options forfeited (unvested)	2,250	(2,250)	\$ 1.59
2004 Plan options expired (vested)	550,748	(550,748)	\$ 5.09
1997 Plan options expired (vested)		(46,416)	\$ 3.00
2004 Plan RSU cancelled (unvested)	15,000		
<b>Balance at December 31, 2010</b>	<b>646,392</b>	<b>6,868,037</b>	<b>\$ 3.05</b>

During the year ended December 31, 2008, the Company granted restricted stock units (RSUs) for a total of 435,000 shares with a grant date fair value of \$1.31 per share. Such RSUs will vest 100% on the third anniversary of the vest commencement date. Prior to this grant in 2008, the Company had no RSUs outstanding. During the year ended December 31, 2010, the Company granted restricted stock units (RSUs) for a total of

**Table of Contents**

150,000 shares with a grant date fair value of \$1.98 per share. There were 15,000, 60,000, and 90,000 RSU shares forfeited during the fiscal years ended December 31, 2010, 2009 and 2008, respectively. There were 420,000 unvested RSU shares as of December 31, 2010. There were no vested RSU shares delivered during the years ended December 31, 2010 and 2009.

Total options exercised during the years ended December 31, 2010, 2009 and 2008 were 139,119, 2,666 and 1,833, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2010, 2009 and 2008 was approximately \$84 thousand, \$1 thousand and \$6 thousand, respectively.

Total restricted stock awards released during the year ended December 31, 2010 and 2009 was zero and 5,000 shares, respectively.

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 December 31, 2010:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding options (vested and expected to vest)	6,191,924	\$ 3.20	6.9	\$ 6,066
Options exercisable	3,409,439	\$ 4.28	5.4	\$ 1,589

**2011 Equity Incentive Plan**

In January 2011, the Company's stockholders approved a 2011 Equity Incentive Plan (the 2011 EIP). The 2011 EIP provides for the issuance of up to 15,000,000 shares of Dynavax Common Stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 EIP is administered by the Company's Board of Directors (the Board), or a designated committee of the Board, and has a term of ten (10) years unless earlier terminated by the Board.

**Employee Stock Purchase Plan**

In January 2004, the Board of Directors and stockholders adopted the 2004 Employee Stock Purchase Plan (the Purchase Plan). The Purchase Plan provides for the purchase of common stock by eligible employees and became effective on February 11, 2004. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the fifteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fourteenth day in February or August).

As of December 31, 2010, 746,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or capital structure. To date, employees acquired 451,676 shares of our common stock under the Purchase Plan. At December 31, 2010, 294,324 shares of our common stock remained available for future purchases.

**Preferred Stock Rights**

On November 4, 2008, the Board of Directors of the Company declared a dividend of one preferred share purchase right (a Right) for each outstanding share of Common Stock, par value \$0.001 per share (the Common Shares), of the Company. The dividend was payable on November 17, 2008 to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the Preferred Shares), at a price of \$6.00 per one one-hundredth of a Preferred Share, subject to adjustment. Upon the acquisition of, or announcement of the intent to acquire, 20 percent or more of the Company's outstanding Common Shares by a

**Table of Contents**

person, entity or group of affiliated or associated persons ( Acquiring Person ), each holder of a Right, other than Rights held by the Acquiring Person, will have the right to purchase that number of Common Shares having a market value of two times the exercise price of the Right. If the Company is acquired in a merger or other business combination transaction or 50 percent or more of its assets or earning power are sold to an Acquiring Person, each holder of a Right will thereafter have the right to purchase, at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right. The Rights plan is intended to maximize the value of the Company in the event of an unsolicited attempt to take over the Company in a manner or on terms not approved by the Company's Board of Directors. The Rights will expire on November 17, 2018, unless the Rights are earlier redeemed or exchanged by the Company.

**Stock-Based Compensation**

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 has also granted performance-based equity awards to certain of our employees under the 2004 Plan and Inducement Plan. As of December 31, 2010, 1,389,832 shares subject to these performance-based vesting criteria were outstanding. 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 Purchase Plan		
	2010	2009	2008	2010	2009	2008
Weighted-average fair value	\$ 1.49	\$ 0.55	\$ 2.29	\$ 1.47	\$ 0.88	\$ 0.93
Risk-free interest rate	1.7%	1.7%	2.7%	0.4%	0.7%	2.4%
Expected life (in years)	4.0	4.0	4.4	0.9	1.1	1.3
Volatility	1.6	1.6	0.8	1.6	1.6	0.8

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, and non-executive level employees were grouped and considered separately for valuation purposes. In 2009, based on employee termination data we adjusted the expected life of the options for both groups of employees to 4 years and this has remained consistent for the year ended December 31, 2010. 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. The dividend yield is 0% for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods of the options. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable. As of December 31, 2010, the total unrecognized compensation cost related to non-vested equity awards amounted to \$4.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.41 years and one year for options and restricted stock units, respectively.

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

	Years Ended December 31,		
	2010	2009	2008
Employees and directors stock-based compensation expense	\$ 2,378	\$ 3,014	\$ 3,183
Non-employees stock-based compensation expense	32	21	22
<b>Total</b>	<b>\$ 2,410</b>	<b>\$ 3,035</b>	<b>\$ 3,205</b>

**Table of Contents**

	Years Ended December 31,		
	2010	2009	2008
Research and development	\$ 632	\$ 1,139	\$ 1,403
General and administrative	1,778	1,896	1,802
<b>Total</b>	<b>\$ 2,410</b>	<b>\$ 3,035</b>	<b>\$ 3,205</b>

**14. Employee Benefit Plan**

We maintain a 401(k) Plan (the 401(k) Plan), which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. To date, we have not contributed to the 401(k) Plan.

**15. Income Taxes**

Income (loss) including noncontrolling interest in SDI before provision for income taxes on a worldwide basis consists of the following (in thousands):

	Years Ended December 31,		
	2010	2009	2008
U.S.	\$ (56,383)	\$ (11,369)	\$ (19,265)
Non U.S.	(929)	475	(1,564)
<b>Total</b>	<b>\$ (57,312)</b>	<b>\$ (10,894)</b>	<b>\$ (20,829)</b>

The U.S. loss including noncontrolling interest in SDI before provision for income taxes for the year ended December 31, 2009 does not include \$19.7 million of consideration paid in excess of carrying value of the noncontrolling interest in SDI. No income tax expense was recorded for the years ended December 31, 2010, 2009 and 2008 due to net operating losses in all jurisdictions. The difference between the income tax benefit and the amount computed by applying the federal statutory income tax rate to loss before income taxes is as follows (in thousands):

	December 31,		
	2010	2009	2008
Income tax benefit at federal statutory rate	\$ (19,486)	\$ (3,722)	\$ (7,082)
State tax	(1,617)	(1,727)	(1,601)
Tax credits	(2,172)	(1,473)	(672)
Deferred compensation charges	318	439	503
Change in valuation allowance	19,863	6,873	13,792
Change in foreign tax rates	22	11	
Change in NOL		(1,439)	(4,810)
Change in the fair value measurements	2,997		
Limitation of NOLs		628	
Other	75	410	(130)
	\$	\$	\$

**Table of Contents**

Deferred tax assets and liabilities as of December 31, 2010 and 2009 consist of the following (in thousands):

	December 31,	
	2010	2009
<b>Deferred tax assets:</b>		
Net operating loss carry forwards	\$ 92,253	\$ 68,641
Research tax credit carry forwards	15,664	13,005
Accruals and reserves	5,492	4,653
Capitalized research costs	12,415	14,208
Deferred revenue	2,726	7,373
Other	1,732	2,914
	130,282	110,794
Less valuation allowance	(130,167)	(110,305)
Total deferred tax assets	115	489
<b>Deferred tax liabilities:</b>		
Acquired intangible assets.	(115)	(489)
Total deferred tax liabilities	(115)	(489)
Net deferred tax assets	\$	\$

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is more likely than not. Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by \$19.9 million, \$6.9 million and \$13.8 million during the years ended December 31, 2010, 2009 and 2008, respectively. The amount of the valuation allowance for deferred tax assets associated with excess tax deductions from stock based compensation arrangements that is allocated to contributed capital if the future tax benefits are subsequently recognized is \$0.4 million.

We have not recorded deferred income taxes applicable to undistributed earnings of a foreign subsidiary that are indefinitely reinvested in foreign operations. Generally, such earnings become subject to U.S. tax upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of the deferred tax liability on such undistributed earnings.

As of December 31, 2010, we had federal net operating loss carryforwards of approximately \$228.5 million, which will expire in the years 2016 through 2030 and federal research and development tax credits of approximately \$9.8 million, which expire in the years 2018 through 2030.

As of December 31, 2010, we had net operating loss carryforwards for California state income tax purposes of approximately \$155.9 million, which expire in the years 2012 through 2030, and California state research and development tax credits of approximately \$8.8 million which do not expire.

As of December 31, 2010, we had net operating loss carryforwards for foreign income tax purposes of approximately \$18.4 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited. As of December 31, 2010, the Company is assessing whether any past equity issuances could trigger a limitation on our ability to use



**Table of Contents**

our net operating losses and tax credits in the future under Sections 382 and 383 of the Internal Revenue Code as enacted by the Tax Reform Act of 1986. For the year ended December 31, 2009, based on the acquisition of the outstanding equity of SDI, there is an annual limitation on the historical net operating losses of SDI and we have adjusted net operating losses accordingly.

We are under audit by the IRS for the tax year 2008. We believe the audit will conclude within the next 12 months and we do not expect any adjustments to materially affect our financial statements. We are also under audit in Germany for the tax years 2005 to 2009. We believe the audit will conclude within three to six months.

In November 2010, the Company received a \$0.7 million grant under The Patient Protection and Affordable Care Act of 2010 covering research and development costs from 2009 and 2010 for three of the Company's qualified therapeutic discovery projects including HEPLISAV. The funds received as a result of this award were recorded as other income in the year ended December 31, 2010.

**16. Selected Quarterly Financial Data (Unaudited; in thousands, except per share amounts)**

	Year Ended December 31, 2010				Year Ended December 31, 2009			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 8,344	\$ 2,191	\$ 11,649	\$ 1,766	\$ 19,344	\$ 15,884	\$ 2,901	\$ 2,189
Net income (loss) attributable to Dynavax	\$ (9,184)	\$ (28,004)	\$ (4,998)	\$ (14,953)	\$ 5,101	\$ 4,110	\$ (9,506)	\$ (30,270)
Basic net income (loss) per share attributable to Dynavax common stockholders	\$ (0.17)	\$ (0.34)	\$ (0.06)	\$ (0.14)	\$ 0.13	\$ 0.10	\$ (0.24)	\$ (0.73)
Shares used to compute basic net income (loss) per share	54,364	82,012	86,826	106,035	39,889	39,923	40,153	41,420
Diluted net income (loss) per share attributable to Dynavax common stockholders	\$ (0.17)	\$ (0.34)	\$ (0.06)	\$ (0.14)	\$ 0.13	\$ 0.10	\$ (0.24)	\$ (0.73)
Shares used to compute diluted net income (loss) per share	54,364	82,012	86,826	106,035	39,889	40,064	40,153	41,420

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES****(a) Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act)) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives.

**Table of Contents**

Based on their evaluation as of the end of the period covered by this report, our management, with the participation of our Chief Executive Officer and our Principal Financial Officer, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

**(b) Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2010. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an attestation report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.



---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Dynavax Technologies Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2010 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 11, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 11, 2011

**(c) Changes in Internal Control Over Financial Reporting**

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

**Table of Contents**

**ITEM 9B. OTHER INFORMATION**

None.

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information required by this Item is incorporated by reference to the sections entitled Proposal One Elections of Directors, Executive Compensation, and Section 16(a) Beneficial Ownership Reporting Compliance in our Definitive Proxy Statement in connection with the 2011 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2010.

We have adopted the Dynavax Code of Business Conduct and Ethics, a code of ethics that applies to our employees, including our Chief Executive Officer, Principal Financial Officer and to our non-employee directors. We will provide a written copy of the Dynavax Code of Business Conduct and Ethics to anyone without charge, upon request written to Dynavax, Attention: Jennifer Lew, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.

**ITEM 11 EXECUTIVE COMPENSATION**

Information required by this Item is incorporated by reference to the section entitled Executive Compensation in the Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the section entitled Security Ownership of Certain Beneficial Owners and Management in the Proxy Statement. Information regarding our stockholder approved and non-approved equity compensation plans are incorporated by reference to the section entitled Equity Compensation Plans in the Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information required by this Item is incorporated by reference to the sections entitled Certain Relationships and Related Transactions and Compensation Committee Interlocks and Insider Participation in the Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information required by this Item is incorporated by reference to the section entitled Audit Fees in the Proxy Statement.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(a) Documents filed as part of this report:**

**1. Financial Statements**

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

**Table of Contents****2. Financial Statement Schedules**

None, as all required disclosures have been made in the Consolidated Financial Statements and notes thereto or are not applicable.

**(b) Exhibits**

<b>Exhibit Number</b>	<b>Document</b>
3.1 <sup>(1)</sup>	Sixth Amended and Restated Certificate of Incorporation
3.2 <sup>(1)</sup>	Amended and Restated Bylaws
3.3 <sup>(2)</sup>	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4 <sup>(12)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5 <sup>(13)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2 <sup>(3)</sup>	Registration Rights Agreement
4.3 <sup>(3)</sup>	Form of Warrant
4.4 <sup>(4)</sup>	Form of Specimen Common Stock Certificate
4.5 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.6 <sup>(2)</sup>	Form of Rights Certificate
4.7 <sup>(6)</sup>	Form of Restricted Stock Unit Award Agreement.
4.8 <sup>(14)</sup>	Form of Amended Warrant
4.9 <sup>(15)</sup>	Form of Warrant
4.10 <sup>(16)</sup>	Registration Rights Agreement dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC.
10.32 <sup>(5)</sup>	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
10.37 <sup>(6)+</sup>	Amended Management Continuity Agreement, dated as of October 3, 2008, between Dynavax Technologies Corporation and Dino Dina
10.38 <sup>(6)+</sup>	Form of Amended Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.39 <sup>(6)</sup>	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and Dynavax Technologies Corporation
10.40 <sup>(7)</sup>	Amendment No. 2 to the Agreement dated September 1, 2006 by and between the Company and AstraZeneca AB ( AZ ) (the Agreement ) dated February 3, 2009 (the Amendment )
10.41 <sup>(8)+</sup>	Amended Management Continuity Agreement, dated as of April 22, 2009, between Dynavax Technologies Corporation and Zbigniew Janowicz
10.42 <sup>(8)</sup>	Amendment No. 4, dated June 1, 2009, to the Exclusive License Agreement, dated October 2, 1998, between Dynavax Technologies Corporation and the Regents of the University of California.

**Table of Contents**

<b>Exhibit Number</b>	<b>Document</b>
10.43 <sup>(9)</sup>	Equity Distribution Agreement, dated August 17, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.
10.44 <sup>(10)</sup>	Amendment to Equity Distribution Agreement, dated September 10, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.
10.45 <sup>(11)+</sup>	Management Service Contract, dated as of January 1, 2005, between Rhein Biotech GmbH and Zbigniew Janowicz
10.46 <sup>(11)+</sup>	Amendment, dated February 5, 2008, to Management Service Contract between Dynavax Technologies Corporation and Zbigniew Janowicz
10.47 <sup>(14)</sup>	Amended Purchase Option Agreement, dated November 9, 2009, between Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.48 <sup>(14)</sup>	Warrant Purchase Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.49 <sup>(14)</sup>	Amended Registration Rights Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.50 <sup>(14)</sup>	Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.51 <sup>(15)</sup>	Settlement Agreement, dated as of March 12, 2010 between Dynavax Technologies Corporation and Merck Sharp & Dohme Corp. f/k/a Merck & Co., Inc.
10.52 <sup>(16)</sup>	Underwriting Agreement, dated April 12, 2010, between Dynavax Technologies Corporation and Wedbush Securities Inc.
10.53 <sup>(17)</sup>	Common Stock Purchase Agreement, dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC.
10.54 <sup>(18)</sup>	Amendment No. 3 to the Agreement dated September 1, 2006 by and between the Company and AZ dated September 30, 2010
10.55 <sup>(19)</sup>	First Amendment to Lease, dated as of May 21, 2004, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.56 <sup>(19)</sup>	Second Amendment to Lease, dated as of October 12, 2010, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.57 <sup>(20)</sup>	Underwriting Agreement, dated October 28, 2010.
10.58 <sup>(21)+</sup>	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010, by and between the Company and Dino Dina, M.D.
10.59 <sup>(21)+</sup>	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010 by and between the Company and J. Tyler Martin, M.D.
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer 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 Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**Table of Contents**

- (1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000- 50577).
- (2) 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 November 6, 2008.
- (3) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (4) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.
- (5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC.
- (6) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC.
- (7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-K for the quarter ended March 31, 2009, as filed with the SEC.
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as filed with the SEC.
- (9) 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.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, as filed with the SEC.
- (11) 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 February 25, 2010.
- (12) 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 January 4, 2010.
- (13) 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 January 5, 2011.

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

- (14) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, as filed with the SEC on March 16, 2010.
- (15) 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 March 16, 2010.
- (16) 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 April 13, 2010.
- (17) 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 September 20, 2010.
- (18) 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 October 4, 2010.
- (19) 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 October 13, 2010.
- (20) 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 October 28, 2010.
- (21) 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 November 23, 2010.

We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

+ Indicates management contract or compensatory plan.



**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

By: /s/ DINO DINA, M.D.  
**Dino Dina, M.D.**

**Chief Executive Officer**

**(Principal Executive Officer)**

Date: March 11, 2011

By: /s/ JENNIFER LEW  
**Jennifer Lew**

**Vice President, Finance**

**(Principal Accounting and Financial Officer)**

Date: March 11, 2011

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ DINO DINA, M.D. <b>Dino Dina, M.D.</b>	Chief Executive Officer  <i>(Principal Executive Officer)</i>	March 11, 2011
/s/ JENNIFER LEW <b>Jennifer Lew</b>	Vice President, Finance <i>(Principal Accounting and Financial Officer)</i>	March 11, 2011
/s/ ARNOLD ORONSKY, PH.D. <b>Arnold Oronsky, Ph.D.</b>	Chairman of the Board	March 11, 2011
/s/ DENNIS CARSON, M.D. <b>Dennis Carson, M.D.</b>	Director	March 11, 2011
/s/ FRANCIS R. CANO, PH.D. <b>Francis R. Cano, Ph.D.</b>	Director	March 11, 2011
/s/ DENISE M. GILBERT, PH.D. <b>Denise M. Gilbert, Ph.D.</b>	Director	March 11, 2011
/s/ MARK KESSEL <b>Mark Kessel</b>	Director	March 11, 2011
/s/ DANIEL L. KISNER, M.D.	Director	March 11, 2011

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

**Daniel L. Kisner, M.D.**

/s/ **J. TYLER MARTIN, M.D.**  
**J. Tyler Martin, M.D.**

Director

March 11, 2011

/s/ **PEGGY V. PHILLIPS**  
**Peggy V. Phillips**

Director

March 11, 2011

/s/ **STANLEY A. PLOTKIN, M.D.**  
**Stanley A. Plotkin, M.D.**

Director

March 11, 2011

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Document</b>
3.1 <sup>(1)</sup>	Sixth Amended and Restated Certificate of Incorporation
3.2 <sup>(1)</sup>	Amended and Restated Bylaws
3.3 <sup>(2)</sup>	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4 <sup>(12)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5 <sup>(13)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2 <sup>(3)</sup>	Registration Rights Agreement
4.3 <sup>(3)</sup>	Form of Warrant
4.4 <sup>(4)</sup>	Form of Specimen Common Stock Certificate
4.5 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.6 <sup>(2)</sup>	Form of Rights Certificate
4.7 <sup>(6)</sup>	Form of Restricted Stock Unit Award Agreement.
4.8 <sup>(14)</sup>	Form of Amended Warrant
4.9 <sup>(15)</sup>	Form of Warrant
4.10 <sup>(16)</sup>	Registration Rights Agreement dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC.
10.32 <sup>(5)</sup>	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
10.37 <sup>(6)+</sup>	Amended Management Continuity Agreement, dated as of October 3, 2008, between Dynavax Technologies Corporation and Dino Dina
10.38 <sup>(6)+</sup>	Form of Amended Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.39 <sup>(6)</sup>	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and Dynavax Technologies Corporation
10.40 <sup>(7)</sup>	Amendment No. 2 to the Agreement dated September 1, 2006 by and between the Company and AstraZeneca AB ( AZ ) (the Agreement ) dated February 3, 2009 (the Amendment )
10.41 <sup>(8)+</sup>	Amended Management Continuity Agreement, dated as of April 22, 2009, between Dynavax Technologies Corporation and Zbigniew Janowicz
10.42 <sup>(8)</sup>	Amendment No. 4, dated June 1, 2009, to the Exclusive License Agreement, dated October 2, 1998, between Dynavax Technologies Corporation and the Regents of the University of California.
10.43 <sup>(9)</sup>	Equity Distribution Agreement, dated August 17, 2009, between Dynavax Technologies Corporation and Webbush Morgan Securities, Inc.
10.44 <sup>(10)</sup>	Amendment to Equity Distribution Agreement, dated September 10, 2009, between Dynavax Technologies Corporation and Webbush Morgan Securities, Inc.
10.45 <sup>(11)+</sup>	Management Service Contract, dated as of January 1, 2005, between Rhein Biotech GmbH and Zbigniew Janowicz

**Table of Contents**

<b>Exhibit Number</b>	<b>Document</b>
10.46 <sup>(11)+</sup>	Amendment, dated February 5, 2008, to Management Service Contract between Dynavax Technologies Corporation and Zbigniew Janowicz
10.47 <sup>(14)</sup>	Amended Purchase Option Agreement, dated November 9, 2009, between Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.48 <sup>(14)</sup>	Warrant Purchase Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.49 <sup>(14)</sup>	Amended Registration Rights Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.50 <sup>(14)</sup>	Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.51 <sup>(15)</sup>	Settlement Agreement, dated as of March 12, 2010 between Dynavax Technologies Corporation and Merck Sharp & Dohme Corp. f/k/a Merck & Co., Inc.
10.52 <sup>(16)</sup>	Underwriting Agreement, dated April 12, 2010, between Dynavax Technologies Corporation and Wedbush Securities Inc.
10.53 <sup>(17)</sup>	Common Stock Purchase Agreement, dated as of September 20, 2010, by and between the Company and Aspire Capital Fund, LLC.
10.54 <sup>(18)</sup>	Amendment No. 3 to the Agreement dated September 1, 2006 by and between the Company and AZ dated September 30, 2010
10.55 <sup>(19)</sup>	First Amendment to Lease, dated as of May 21, 2004, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.56 <sup>(19)</sup>	Second Amendment to Lease, dated as of October 12, 2010, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.57 <sup>(20)</sup>	Underwriting Agreement, dated October 28, 2010.
10.58 <sup>(21)+</sup>	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010, by and between the Company and Dino Dina, M.D.
10.59 <sup>(21)+</sup>	Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010 by and between the Company and J. Tyler Martin, M.D.
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer 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 Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**Table of Contents**

- (1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000- 50577).
- (2) 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 November 6, 2008.
- (3) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (4) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.
- (5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC.
- (6) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC.
- (7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-K for the quarter ended March 31, 2009, as filed with the SEC.
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as filed with the SEC.
- (9) 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.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, as filed with the SEC.
- (11) 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 February 25, 2010.
- (12) 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 January 4, 2010.
- (13) 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 January 5, 2011.

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

- (14) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, as filed with the SEC on March 16, 2010.
- (15) 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 March 16, 2010.
- (16) 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 April 13, 2010.
- (17) 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 September 20, 2010.
- (18) 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 October 4, 2010.
- (19) 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 October 13, 2010.
- (20) 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 October 28, 2010.
- (21) 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 November 23, 2010.

We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

+ Indicates management contract or compensatory plan.