

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 16, 2010

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## 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, 2009

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*

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*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:**

**Common Stock, par value \$0.001 per share**

*(Title of Class)*

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 registrant 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

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The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2009 as reported on the Nasdaq Capital Market, was approximately \$50,119,635. 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, 2010, the registrant had outstanding 54,359,311 shares of common stock.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the registrant's 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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**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, our future research and development, 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 of these terms or other 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 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 diseases, asthma and inflammatory and autoimmune diseases. The Company's lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly and with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; our Universal Flu vaccine; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs partnered with AstraZeneca and GlaxoSmithKline ( GSK ). 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. 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 and control chronic inflammation. ISS activate the innate immune response by specifically targeting TLR9, which is found on a specialized subset of immune cells.

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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 viral disease and bacterial infections, ISS are 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 viral and respiratory diseases, ISS can be used alone to modify the course of this 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.

These first-in-class endosomal TLR inhibitors specifically target two types of immune cells, B cells and Plasmacytoid dendritic cells (PDC) that selectively express TLR7 and TLR9. These receptors play a key role in the overproduction of interferon alpha by PDC and in the presence of anti-nuclear autoantibodies generated by B cells, which are hallmarks of some autoimmune diseases such as lupus. Because our TLR inhibitors target only TLR7 and TLR9, they do not inhibit all sources of interferon nor do they affect all antibody responses from B cells. This suggests that these TLR inhibitors would not cause broad immunosuppression.

**Table of Contents****Primary 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>
<b>Development Programs</b>			
HEPLISAV	Hepatitis B prevention	Phase 3	Dynavax
Universal Flu vaccine	Influenza prevention	Preclinical	Novartis (Supply and Option Agreement); NIH
SD-101	Hepatitis C infection	Phase 1b	Dynavax
DV-601	Hepatitis B infection	Phase 1b	Dynavax
<b>Partnered Programs</b>			
AZD1419	Asthma	Preclinical	AstraZeneca AB
DV1179	Autoimmune and inflammatory diseases	Preclinical	GlaxoSmithKline; NIH

**HEPLISAV Hepatitis B Vaccine**

Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly and 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, 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.

In September 2009, we initiated a Phase 3 trial in chronic kidney disease patients and in February 2010, we initiated a Phase 3 lot-to-lot consistency trial in adults over 40 years of age. These studies are directed toward fulfilling licensure requirements in the U.S, Canada and Europe. Data from these trials are expected in mid-2011.

In order to continue the ongoing clinical trials for HEPLISAV, we must raise significant additional funds in the near term. While we are actively seeking financing alternatives, we cannot assure that sufficient funding will be available, or even if available, that such funding will be on terms acceptable to us. If adequate funds are not available in the near term, we have developed contingency plans that would require us to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

**Clinical Results**

Over 2,500 individuals have been vaccinated with HEPLISAV to date. In the largest clinical trial conducted to date, known as PHAST (Phase 3 HepelisAv Short-regimen Trial), HEPLISAV met its primary endpoint. The multi-center PHAST trial evaluated more than 2,400 subjects from 11 to 55 years of age in Canada and Germany. This Phase 3 trial randomized subjects three to one and evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month, compared to a three-dose regimen of Engerix-B<sup>1</sup> 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.

<sup>1</sup> Engerix-B<sup>®</sup> is a registered trademark of GlaxoSmithKline.

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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 95.1% of subjects who received two doses of HEPLISAV at 0 and 1 month developed protective antibody to hepatitis B when measured at 12 weeks. This compared to 81.1% of subjects who received three doses of Engerix-B at 0, 1, and 6 months when measured 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 HEPLISAV appeared similar to 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 percent for the HEPLISAV group, compared to 81.4 percent for the Engerix-B group. The incidence of Serious Adverse Events (SAEs) was 1.5 percent for the HEPLISAV group, compared to 2.1 percent 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 FDA following the 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.

### ***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 low responders – current vaccines fail to provide seroprotection to a large percentage of persons over 60 years of age and to immunocompromised persons, such as end-stage renal disease (ESRD) patients; and

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

HEPLISAV is designed to address the limitations of current vaccines by delivering enhanced protection more rapidly, over a longer duration and with fewer doses than currently licensed vaccines.

We estimate the current worldwide market for adult monovalent hepatitis B vaccines is approximately \$525 million annually. This market is primarily comprised of GSK's Engerix-B and Merck's Recombivax-HB. An estimated \$330 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, people with high-risk sexual behavior or injection drug use, and chronic liver disease patients.

HEPLISAV is being developed initially for patients less responsive to current licensed vaccines, including those with CKD, HIV or chronic liver disease. The chronic kidney disease market is large, growing rapidly, and is widely recommended for vaccination. In 2006, there were approximately 750,000 ESRD patients in the United States and the 5 major European markets and approximately 150,000 new patients are added annually. These patients do not respond well to current vaccines, so a typical regimen calls for 8 doses of Engerix-B (vs. 3 doses in the general population). Even with this regimen, approximately 35% of these immunocompromised ESRD patients do not respond to vaccination and 20% 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.



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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. Patients do not respond well to current vaccines, so aggressive vaccination regimens and boosters are common. There are approximately 2 million adults living with HIV in the U.S. 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.

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, and travelers because HEPLISAV provides higher levels of protection in 30 days compared to 6 months for current licensed vaccines.

### **Universal Flu Vaccine**

Our Universal Flu vaccine is in preclinical development and is designed to offer protection against divergent strains as well as increase the efficacy and potentially reduce the dose of standard flu vaccine. This unique approach is based on combining two highly conserved antigens and our proprietary second-generation ISS agonist with standard flu vaccines:

Standard flu vaccine Our proprietary component, NP and M2e linked to our TLR9 agonist, is combined with the standard flu vaccine, which generates neutralizing antibodies. Our proprietary component could be combined with any standard 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 expected to offer protection against divergent 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 protective antibodies for protection against divergent strains.

Our proprietary second-generation TLR9 agonist to enhance efficacy and enable dose-sparing NP and M2e are linked to our proprietary second-generation TLR9 agonist, which has demonstrated the potential to boost the immune response and enable dose sparing, which could extend the quantity of standard flu vaccine available.

Our research and development program has been partially funded by grants from the National Institutes of Health (NIH). Dynavax has established a worldwide supply and option agreement with Novartis Vaccines and Diagnostics, Inc. for our Universal Flu vaccine program.

### ***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.

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Our Universal Flu vaccine candidate is designed to offer protection against divergent influenza strains, increase the efficacy of standard vaccines, and potentially reduce the dose 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. 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.

#### ***Clinical Results***

Data from the Phase 1b study of SD-101 in 34 chronically infected, treatment-naïve, genotype 1 HCV patients show:

A safety and tolerability profile that compares favorably to that of IFN-alpha, at all four dose levels tested;

A dose-dependent antiviral response, with 100% of patients at the highest dose experiencing a greater than one (1) log reduction in viral load; and

Substantial, dose-related increases in the expression of key antiviral genes (MX-B and ISG-54k) and genes indicating enhanced immunity (IP-10 and MCP-1).

The *in vitro* data from a study of the drug in human blood cells demonstrate that compared to first-generation TLR9 agonists, SD-101 stimulates 20-fold higher levels of both IFN-alpha and IFN-lambda, two classes of IFNs with potent activity against HCV.

In January 2010, we announced the completion of the acquisition of Symphony Dynamo, Inc., which provided Dynavax full development and commercialization rights to SD-101. As such, SD-101 is now part of the portfolio of development programs that are available for partnership.

#### ***Commercial Opportunity***

According to the World Health Organization, there are 170 million people worldwide chronically infected with HCV. We estimate the current worldwide market for HCV therapeutics is over \$3 billion annually. While there is no vaccine available to prevent HCV, current therapy includes pegylated interferon alpha and the antiviral drug ribavirin. Both of these therapies may cause significant side effects and are only effective in treating half of all patients infected with HCV.

Products offering enhanced efficacy and safety profiles are anticipated to increase the number of patients seeking and continuing treatment. SD-101, used in combination with current and/or emerging therapies, may reduce HCV viral replication and induce a long-lasting immune response.

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

DV-601 is our proprietary hepatitis B therapy and is in a Phase 1b clinical trial. This treatment approach combines both the surface and core hepatitis B virus (HBV) antigens with an adjuvant. DV-601 may induce a potent immune response against HBV-infected cells and offer a more effective and shorter duration therapeutic option for patients chronically infected with HBV. We have retained all commercial rights to this product.

#### ***Commercial Opportunity***

Over 350 million individuals worldwide are chronically infected with HBV, which can lead to cirrhosis of the liver and hepatocellular carcinoma. The current worldwide market for HBV therapeutics is estimated to be over



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\$1 billion annually and available therapies have modest efficacy. Current treatment aims to halt progression of the disease and consists of either indefinite use of antiviral medication and/or treatment with pegylated interferon-alpha. Approximately 30% of treated patients achieve treatment goals and fewer than 10% are ever considered cured. Antiviral therapy may need to continue indefinitely to sustain treatment goals and is increasingly subject to antiviral resistance while treatment with interferon-alpha can cause significant side effects.

Our HBV therapy, used in combination with existing antiviral therapies, is intended to induce a potent immune response against HBV-infected cells in the liver with the objective of eradicating HBV infection and thereby provide a more effective and shorter duration therapeutic option for chronically infected patients.

### **AZD1419 Asthma Therapy**

Together with our partner AstraZeneca, we are developing AZD1419, a novel candidate drug for asthma. 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. We are developing ADZ1419 under our worldwide collaboration with AstraZeneca to discover, develop, and commercialize products for asthma and COPD.

#### ***Commercial Opportunity***

According to the World Health Organization, asthma affects 300 million people worldwide. Asthma is a chronic disease of the lungs and is caused primarily by allergic inflammation of the airways. In addition, 210 million people worldwide are affected by COPD, a term used to describe chronic lung diseases that limit airflow in the lungs. Analysts estimate the current worldwide market opportunity for asthma and COPD therapies to be over \$15 billion annually.

Current asthma and COPD therapies include corticosteroids and bronchodilators, which treat the symptoms of these respiratory diseases. AZD1419 is intended to be a disease modifying therapy that has demonstrated the potential to inhibit and induce durable changes to the allergic response that causes asthma symptoms.

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

Our IRS program focusing on TLRs, which are key receptors of the innate immune system that can induce strong inflammatory responses, is based on our product candidate DV1179, a bifunctional inhibitor of TLR7 and TLR9. Dynavax and GlaxoSmithKline have entered into a worldwide strategic alliance to discover, develop, and commercialize DV1179 and other novel TLR inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We will conduct research and early clinical development in up to four programs and are eligible to receive future potential development and commercialization milestones. 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 will carry out further development and commercialization of these products. We will receive tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one specified product.

#### ***Commercial Opportunity***

Over 20 million individuals in the U.S. and Europe have autoimmune diseases such as lupus, psoriasis, and rheumatoid arthritis. Key biologic drugs used to treat these conditions generate over \$15 billion in worldwide sales each year.

### **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

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strategy is to establish partnerships with leading pharmaceutical companies and enter into funding agreements. Our pharmaceutical partners provide valuable resources, development expertise, and commercial 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 also 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.

### **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. AstraZeneca has the right to sublicense its rights upon 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 we have initiated 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. Either party also may terminate the agreement in the event of insolvency or a change of control of the other party.

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

In July 2008, we entered into a supply and option agreement with Novartis for 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 U.S. and receive product royalties outside of the U.S. 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 U.S.

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 development events or failures, or (d) Dynavax ceases development of the product candidate for a certain length of time.

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

For our TLR agonist programs, since 2003 we have been awarded \$11.6 million in grants from the NIH which have helped fund our research and development, of which a substantial portion has been used to support the development of our Universal Flu vaccine. Although the NIH provides program support, we have the right to seek strategic partners for the future development and commercialization of our Universal Flu vaccine. 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 disease models. NIAID is funding 100 percent of the total \$17 million cost of our program under Contract No. HHSN272200800038C and has so far allotted \$4.9 million of that amount for work scheduled through September, 2010. 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.

For our TLR inhibitor programs, since 2004 we have been awarded \$2.8 million in grants from the NIH and Alliance for Lupus Research. Certain of these grants have been extended through June 2010.

### **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, 2009, our intellectual property portfolio included 12 issued U.S. patents, over 50 issued foreign patents and over 200 additional pending US 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 2029.

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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 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. 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. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, 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 in the United States. Litigation or any of these 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 \$1.5 million in

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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 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 developed, approved and commercialized, will compete directly with three-dose marketed vaccines produced by GSK, Merck & Co., ( Merck ) and Crucell N.V., among others. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in 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 MSD, MedImmune/AstraZeneca and CSL Ltd. In addition, there are several companies developing potentially competing universal vaccines for influenza, including Acambis, VaxInnate, Merck and Vical.

Our hepatitis C therapy, SD-101, if developed, approved, and commercialized, may compete directly with interferon alpha and indirectly with ribavirin, products currently marketed by Roche and Merck. Other companies, such as Vertex Pharmaceuticals, Inc./Tibotec Pharmaceuticals, Gilead Sciences, Inc. (Gilead), Merck, Human Genome Sciences, Inc./Novartis, and Roche/Pharmasset, Inc./InterMune, Inc. are developing direct acting antiviral therapy, including protease inhibitors and polymerase inhibitors, and long-acting interferons. As these products may enter the market within the next two 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, including Pharmasset and LG Life Sciences, as well as companies developing therapy vaccines, including Emergent BioSolutions and Genexine Co., Ltd.

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 monoclonal antibodies, including those marketed by Merck, Genentech, Inc. (Genentech), Novartis, AstraZeneca, Schering-Plough and GSK. In addition, directly competing products are in development by Sanofi-aventis and Idera Pharmaceuticals.

Our therapy for autoimmune and inflammatory diseases, DV-1179, 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, Biogen Idec, Roche and Abbott Laboratories. In addition, our product would compete with



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generic drugs commonly used to treat autoimmune diseases, including corticosteroids, NSAIDs, antimalarials and immunosuppressive agents. Other companies, such as MedImmune, Genentech, Idera, Pfizer, Human Genome Sciences/GSK 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.

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 Dynavax. 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 U.S. and other countries. In the U.S., 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 U.S. are similar to steps required in most other countries and include but are not limited to the following:

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

submission to the FDA of an investigational new drug application, or IND, 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;

the submission of a new drug application, or NDA, or a biologics license application, or 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, manufacturing information, and other supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. 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. 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 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

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exploit patented products or technologies. Delays can occur at any stage of drug development and as 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 replicated. The results of the non-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an investigational new drug application, which must be approved by the FDA before we can commence clinical investigations in humans. Unless the FDA objects to an investigational new drug application, the investigational new drug 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 investigational new drug 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,

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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 biological product standards. Failure to comply with the statutory and regulatory requirements subjects the

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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 good manufacturing practice 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 good manufacturing practice 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 U.S., 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, 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 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 safety, quality and efficacy.

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 \$38.7 million for the year ended December 31, 2009, \$44.8 million for the year ended December 31, 2008 and \$65.9 million for the year ended December 31, 2007.

## **Employees**

As of December 31, 2009, we had 130 full-time employees, including 25 Ph.D.s, 4 M.D.s and 14 others with advanced degrees. Of the 130 employees, 103 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.

## **ITEM 1A. RISK FACTORS**

This Annual Report on Form 10-K contains forward-looking statements concerning our future products, product candidates, development plans, expenses, revenues, liquidity and cash needs, as well as our commercialization 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.

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$259.6 million as of December 31, 2009. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; whether our future development efforts will be sufficient to support product approval; or whether the market for HEPLISAV will be substantial enough for us to reach profitability.

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

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

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

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

***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, there may be a question as to whether we would 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 will have to raise significant additional funds in the near term. 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.

We are engaged in active and ongoing discussions to pursue additional capital through a combination of public and private equity offerings and strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources.

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 on hand at December 31, 2009, anticipated revenues, reductions in our current spending levels, and the successful completion of ongoing financing activities. Our failure to raise capital in the near term or to timely reduce costs could shorten this period.

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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 near term,

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we have developed contingency plans that would require us to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

***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 for the year ended December 31, 2009 a statement with respect to our ability to continue as a going concern. However, 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. The reaction of investors to the inclusion of a going concern statement by our independent auditors, our lack of cash resources, and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into strategic alliances.

***We may not realize the expected benefits of our initiatives to reduce costs across our operations.***

We may pursue a number of initiatives to reduce costs across our operations, including workforce reductions and renegotiation of our leases and other long-term obligations. We may incur some amount of restructuring charges as we implement these cost reduction initiatives and may not realize some or all of the expected benefits of our future initiatives to reduce costs. In addition to restructuring or other charges, the changes may result in significant disruptions in our operations now and in the future as a result of these initiatives.

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

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

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. Despite the time and money expended, regulatory approvals are uncertain. In addition, our products will compete in highly competitive markets and 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 of the product may significantly limit the commercial opportunity for such product.

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

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with

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good clinical practice requirements, concerns regarding health risks to test subjects, failure to enroll patients in a timely manner, or delays due to 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.

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.

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

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

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

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

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



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Our most advanced product candidate in clinical trials is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials

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produce serious adverse safety data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. For example, from March 2008 until September 2009, the two IND applications for HEPLISAV were placed on clinical hold by the FDA following a serious adverse event that occurred in one of our clinical trials. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease but the other IND application for HEPLISAV remains on clinical hold. In addition, most of our clinical product candidates contain ISS, and a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

***We rely on our facility in Düsseldorf, Germany and third parties to supply materials necessary to manufacture our clinical product candidates for our clinical trials. If we reduce our clinical product candidates, we may not require this manufacturing capacity. We have limited experience in manufacturing our product candidates in commercial quantities. Failure to comply with applicable regulatory requirements or loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.***

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

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

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

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current good manufacturing practices 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 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.

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 in a reasonable time frame, if at all.

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

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

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

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

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

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

the presence of other competing approved therapies;

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

the relative convenience and ease of administration of the product;

the strength of our sales, marketing and distribution support;

the price and cost-effectiveness of the product; and

sufficient third-party reimbursement.

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

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

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

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

our shortage of capital resources may impact a willingness on the part of potential companies to collaborate;

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our contracts for collaborative arrangements are terminable for convenience 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 do not have day to day control over the activities of our partners and have limited control over their decisions;

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

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

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

our partners may not comply with applicable government regulatory requirements.

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

***The financial terms of future collaborative or licensing or financing arrangements could result in significant 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 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 significant 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 diseases, asthma and inflammatory and autoimmune diseases. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

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

collaborative arrangements, sell our product candidates or generate revenues.

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*The loss of key personnel, including our Chief Executive Officer, 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. We currently have no key person insurance on any of our employees.

*Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel.*

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. There is intense competition for the services of these 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.

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

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

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

compliance with varying international regulatory requirements, laws and treaties;

securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

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

adverse tax consequences;

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

regional and geopolitical risks.

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

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

Our current research and development efforts depend upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes



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regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments in order to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are not able to cure or obtain waivers for such failures or amend the term of such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates.

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

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. We are involved in various interference and other administrative proceedings related to our intellectual 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 will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV in the U.S. while these patents remain in force, Merck, GSK or the Institut Pasteur may bring claims against us.

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

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

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

Our success depends on our ability to:

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

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

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

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

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

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;

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

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

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

***We 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

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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 product 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.

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

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

The current administration has stated that it is committed to reforming the health care system in the U.S. and the Senate and House of Representatives each have passed a health care reform bill. However, the differences between the two bills must be reconciled and we are unable to predict whether a final bill will be passed and, if enacted, what impact reform legislation will have on our business or future prospects. It is likely that any legislation that is enacted will affect the biopharmaceutical industry and the uncertainty as to the nature and scope of any proposed reforms limits our ability to forecast changes that may affect our business and to manage our business accordingly. This uncertainty also may make it more difficult for us to enter into collaboration agreements for our product candidates and to obtain financing for future development of our product candidates.

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

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

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*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;

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

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

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

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

volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In October 2008, we experienced a decline in our market capitalization of nearly 80% based on the FDA's communication to us regarding the continuation of a clinical hold on two U.S. IND applications for HEPLISAV. While the FDA has removed the clinical hold on the IND application for individuals with chronic kidney disease, our market capitalization remains well below levels prior to the announcement of the FDA's clinical hold. In November 2008, we transferred our listing of Dynavax shares to The NASDAQ Capital Market from The NASDAQ Global Market. We may be delisted from The NASDAQ Capital Market if our share price or market value of publicly held shares does not meet certain thresholds. In addition, securities class action

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litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

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

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

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

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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 may need to implement additional financial and accounting systems, procedures or controls as our business and organization changes and to comply with reporting requirements.***

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

***Future sales of our common stock 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, 2009, we had 54,279,270 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.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended (the Securities Act), 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.

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

Entities affiliated with Symphony Capital Partners, L.P. (Symphony) currently collectively control approximately 8,340,800 shares of our common stock and warrants to purchase approximately 1,283,200 shares





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of our common stock. Based on our currently outstanding shares of common stock, these stockholders own approximately 15% of our total outstanding shares of common stock. If these stockholders exercise the warrants to purchase approximately 1,283,200 shares of our common stock, assuming no other issuances of shares, based on our currently outstanding shares of common stock, these stockholders would own approximately 17% of our total outstanding shares of our common stock. In addition, 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 Symphony Dynamo Holdings LLC ( 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 has designated Mark Kessel, a partner of Symphony, as its designee and Mr. Kessel has been appointed to our Board of Directors. The independent nominee has not yet been designated. 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**

We lease approximately 67,000 square feet of laboratory and office space in Berkeley, California (the Berkeley Lease) under agreements expiring in September 2014, of which approximately 3,000 square feet is subleased through August 2010. The Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany (the Düsseldorf Lease) under lease agreements expiring in March 2023.

### **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.

**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>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
<b>2008</b>		
First Quarter	\$ 6.55	\$ 1.87
Second Quarter	\$ 2.59	\$ 1.40
Third Quarter	\$ 2.04	\$ 0.97
Fourth Quarter	\$ 2.60	\$ 0.15

As of March 8, 2010, there were approximately 111 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**

On December 30, 2009, the Company, Symphony and Holdings entered into a series of related agreements with us to cancel warrants previously issued in April 2006 in exchange for new warrants to purchase 2 million shares of our common stock at a price of \$1.94 per share ( Warrants ), representing a 25% premium over the applicable 30-day trading range average of \$1.55 per share through November 9, 2009. Also in connection with the Company's amendment of the Purchase Option Agreement and acquisition of SDI, the Company issued 13 million shares of its common stock to Holdings ( Shares ). We filed a registration statement on Form S-3 (File No. 333-164255) on January 8, 2010 covering the resale of shares of common stock including the common stock subject to purchase upon exercise of the warrants issued to Holdings and its affiliates. The Shares and Warrants were issued pursuant to an exemption from registration under Rule 506 promulgated under Regulation D.

**Use of Proceeds from Sales of Registered Securities**

On August 17, 2009 the Company entered into an equity distribution agreement (the Agreement ) with Wedbush Morgan Securities, Inc. ( Wedbush ) pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. We filed the related prospectus supplement to Form S-3 (File No. 333-137608) on August 17, 2009. During the period from August 17, 2009 through October 26, 2009, we sold through Wedbush as our sales agent an aggregate of 1,281,100 shares of common stock for net proceeds

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of \$2.2 million after deducting commissions paid to Wedbush and offering expenses. The Company later filed another prospectus supplement to Form S-3 (File No. 333-139664) on October 30, 2009 for the remaining portion of \$12.2 million. As of December 31, 2009, we could offer and sell from time to time through Wedbush up to an additional \$12.2 million in aggregate offering proceeds of our common stock under the Agreement.

Pursuant to agreements with Deerfield, we issued to Deerfield Management and their affiliates the following warrants to purchase shares of our common stock:

Warrant Issuance Date	Shares Issued (in thousands)	Form S-3 File No.	Expiration Date	Exercise Price per Share
July 18, 2007	1,250	333-145836 <sup>(1)</sup>	2/26/2014	\$ 5.13
October 18, 2007	1,300	333-147455 <sup>(2)</sup>	2/26/2014	\$ 1.68
December 27, 2007	300	333-149117 <sup>(3)</sup>	2/26/2014	\$ 5.65
December 27, 2007	700	333-149117 <sup>(3)</sup>	2/26/2014	\$ 1.68
<b>Total</b>	<b>3,550</b>			

- (1) We filed a registration statement on Form S-3 (File No. 333-145836) on August 31, 2007 with the Securities and Exchange Commission and the related prospectus supplement dated September 14, 2007.
- (2) We filed a registration statement on Form S-3 (File No. 333-147455) on November 16, 2007, as amended on November 30, 2007 with the Securities and Exchange Commission and the related prospectus supplement dated December 5, 2007.
- (3) We filed a registration statement on Form S-3 (File No. 333-149117) on February 8, 2008 with the Securities and Exchange Commission and the related prospectus supplement dated May 9, 2008.

On December 6, 2006, pursuant to agreements with Azimuth Opportunity Ltd., we issued 1,663,456 shares at a weighted average price of \$9.02 per share and realized aggregate proceeds of \$15.0 million. The shares were issued pursuant to the Registration Statement on Form S-3 (File No. 333-127930) filed on August 29, 2005 with the Securities and Exchange Commission and the related prospectus supplement dated December 6, 2006.

On October 10, 2006, we completed an underwritten public offering of 7,130,000 shares of common stock, including 930,000 shares subject to the underwriters' over-allotment option at a public offering price of \$4.40 per share and realized aggregate proceeds of \$31.4 million. The offering was made pursuant to the Registration Statement on Form S-3 (File No. 333-137608) filed on September 27, 2006 with the Securities and Exchange Commission and the related prospectus supplement dated October 4, 2006.

On November 10, 2005, we completed an underwritten public offering of 5,720,000 shares of common stock, including 720,000 shares subject to the underwriters' over-allotment option at a public offering price of \$6.25 per share and realized aggregate proceeds of \$35.7 million. The offering was made pursuant to the Registration Statement on Form S-3 (File No. 333-127930) filed on August 29, 2005 with the Securities and Exchange Commission and the related prospectus supplement dated October 10, 2005.

On February 24, 2004, we completed our initial public offering of 6,900,000 shares of common stock, including 900,000 shares subject to the underwriters' over-allotment option at a public offering price of \$7.50 per share and realized aggregate proceeds of \$51.8 million. Our registration statement on Form S-1 (Reg. No. 333-109965) was declared effective by the Securities and Exchange Commission on February 11, 2004.

We retain broad discretion over the use of the net proceeds received from our offerings. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product candidate development and commercialization efforts and the amount of cash used by our operations.



**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, 2009, 2008 and 2007 and the Consolidated Balance Sheets Data as of December 31, 2009 and 2008 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, 2006 and 2005 and the Consolidated Balance Sheets Data as of December 31, 2007, 2006 and 2005 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.

	2009(1)	Years Ended December 31,			2005
		2008(1)	2007(1)	2006(1)	
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ 40,318	\$ 37,094	\$ 14,093	\$ 4,847	\$ 14,655
Operating expenses:					
Research and development(2)	38,708	44,771	65,888	50,116	27,887
General and administrative	15,745	15,463	18,293	14,836	9,258
Acquired in-process research and development(3)				4,180	
Amortization of intangible assets	980	980	1,004	698	
Total operating expenses	55,433	61,214	85,185	69,830	37,145
Loss from operations	(15,115)	(24,120)	(71,092)	(64,983)	(22,490)
Interest and other income, net	112	1,741	4,165	3,287	2,125
Loan forgiveness(4)		5,000			
Interest expense(5)	(124)	(9,157)	(1,719)	(99)	(190)
Net loss.	(15,127)	(26,536)	(68,646)	(61,795)	(20,555)
Consideration paid in excess of carrying value of the noncontrolling interest in Symphony Dynamo, Inc. (SDI)	(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	\$ (30,565)	\$ (20,829)	\$ (59,971)	\$ (52,052)	\$ (20,555)
Basic and diluted net loss per share attributable to Dynavax common stockholders	\$ (0.76)	\$ (0.52)	\$ (1.51)	\$ (1.61)	\$ (0.79)
Shares used in computing basic and diluted net loss per share attributable to Dynavax common stockholders	40,350	39,819	39,746	32,339	25,914

(1) Our net loss for the years ended December 31, 2009, 2008, 2007 and 2006 includes approximately \$3.0 million, \$3.2 million, \$3.5 million, and \$3.2 million respectively, in stock-based compensation expense for our employee stock option and employee stock purchase plans that we recorded as a result of adopting Topic 718, *Compensation-Stock Compensation*.

(2) Research and development expenses for the year ended December 31, 2007 include an impairment charge of approximately \$0.4 million for certain intangible assets and related inventory.

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

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- (4) 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.
- (5) 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. For a description of these charges, see Note 8 to the Consolidated Financial Statements.

	2009	2008	December 31, 2007 (In thousands)	2006	2005
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and marketable securities	\$ 36,720	\$ 43,367	\$ 56,617	\$ 72,831	\$ 75,110
Investments held by Symphony Dynamo, Inc.		25,109	31,631	13,363	
Working capital	24,404	35,688	82,035	75,985	71,941
Total assets	50,470	90,623	120,449	102,890	80,093
Noncontrolling interest in Symphony Dynamo, Inc.		2,634	8,341	2,016	
Accumulated deficit	(259,637)	(248,743)	(227,914)	(167,943)	(115,891)
Total Dynavax stockholders' equity	6,376	13,522	30,790	77,056	74,363

**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 diseases, asthma and inflammatory and autoimmune diseases. The Company's lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly and with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; our Universal Flu vaccine; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs partnered with AstraZeneca and GlaxoSmithKline (GSK). 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.

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### **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, investments, asset impairment, the estimated useful life of assets, income taxes and contingencies. We base our estimates on historical experience and on 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 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. Advance payments received in excess of amounts earned are classified as deferred revenue until earned. 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.

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.



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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. Any amounts received in advance of performance are recorded as deferred revenue until earned.

### ***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.

### ***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 forfeiture rate, 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 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 year ended December 31, 2009. 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 amounts are 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 valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. The

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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;

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***

On April 18, 2006, we, Symphony Capital Partners, L.P. and Symphony Dynamo Holdings LLC ( Holdings ) entered into a transaction involving a series of related agreements providing for the advancement of specific Dynavax immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the Programs ). Pursuant to these agreements, Symphony Capital Partners, L.P. and certain of its affiliates (collectively, Symphony ) formed Symphony Dynamo, Inc ( 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 owns 100% of the equity of Holdings, which owns 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 ). The Original Purchase Option would have been exercisable for a price of \$106.9 million as of October 1, 2009, which purchase price would have increased quarterly by a predetermined amount up to \$144.1 million if the Original Purchase Option were exercised on April 18, 2011. If not exercised, the Original Purchase Option would have expired on April 18, 2011. The exercise price of the Original Purchase Option could have been paid for in cash or a combination of cash and our common stock. 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, and granted certain registration rights to Holdings pursuant to a registration rights agreement.

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We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (the Program Option ) during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program. We have 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 have agreed to with Holdings.

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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.

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 have consolidated the financial position and results of operations of SDI. We have not consolidated Holdings because we believe our variable interest, the Purchase Option, is on the stock of SDI. We believe SDI is a VIE because we have 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.

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, pursuant to FIN 46R's requirements, we are most closely associated with SDI. We concluded that we are 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 are 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.

Symphony was required to absorb the development risk for its equity investment in SDI. Symphony's equity investment in SDI was classified as noncontrolling interest in the consolidated balance sheet. The noncontrolling interest held by Symphony has been 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.

Net losses incurred by SDI and charged to the noncontrolling interest were \$4.2 million, \$5.7 million and \$8.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

In December 2007, the FASB 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 Dynavax's common stockholders would have increased by \$1.9 million and the loss per share attributable to Dynavax common stockholders would have increased by \$0.05, during the year ended December 31, 2009.

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In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the purchase option. We completed the acquisition of all of the outstanding equity of SDI pursuant to the amended purchase option on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to the Symphony Investors: (i) 13 million shares of common stock; (ii) 5 year warrants to purchase 2 million shares of common stock with an exercise price of \$1.94 per share; (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; and (iv) 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. The outstanding warrants to purchase 2 million shares of common stock held by the Symphony Investors 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 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 Dynavax for the year ended December 31, 2009.

The fair value of the Dynavax 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 solely 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 an 18% rate.

Changes in the fair value of the acquisition-related contingent consideration liability subsequent to the December 30, 2009 acquisition date will be 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.

## **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.

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The following is a summary of our revenues for the years ended December 31, 2009, 2008 and 2007 (in thousands, except for percentages):

Revenues:	Years Ended December 31,			Increase (Decrease) from 2008 to 2009		Increase (Decrease) from 2007 to 2008	
	2009	2008	2007	\$	%	\$	%
Collaboration revenue	\$ 35,534	\$ 31,666	\$ 9,315	\$ 3,868	12%	\$ 22,351	240%
Grant revenue	3,477	2,999	3,046	478	16%	(47)	(2)%
Services and license revenue	1,307	2,429	1,732	(1,122)	(46)%	697	40%
Total revenues	\$ 40,318	\$ 37,094	\$ 14,093	\$ 3,224	9%	\$ 23,001	163%

Collaboration revenue in 2009 included recognition of \$28.5 million of deferred revenue associated with the upfront payment from Merck, which was accelerated through June 2009 following Merck's termination of the collaboration for HEPLISAV in December 2008. Total revenues for the year ended December 31, 2009 increased by \$3.2 million, or 9%, over the same period in 2008 primarily due to the accelerated recognition of deferred revenue upon termination of the Merck collaboration. In addition, collaboration revenue from AstraZeneca included the recognition of \$1.7 million of deferred revenue related to a milestone payment received in the third quarter of 2008. Grant revenue for the year ended December 31, 2009, increased over the same periods in 2008 due primarily to revenues earned from the National Institute of Health (NIH) contract we were awarded in September 2008. Services and license revenue of \$1.3 million for the year ended December 31, 2009, respectively, were derived primarily from research and development services provided to customers of Rhein Biotech GmbH (Rhein or Dynavax Europe).

Total revenues for the year ended December 31, 2008 increased by \$23.0 million, or 163%, over the same period in 2007 primarily due to an increase in revenue recognized from our collaboration agreements with Merck and AstraZeneca. Collaboration revenue in 2008 included the recognition of \$5 million of previously deferred revenue associated with the upfront payment from Merck, a portion of which was accelerated due to Merck's termination of the collaboration in December 2008. In addition, collaboration revenue from AstraZeneca increased by \$2 million, resulting from the receipt of a milestone payment in the third quarter of 2008. Grant revenue for the year ended December 31, 2008 included revenue recognized from NIH awards to continue development of our Universal Flu vaccine, a therapy for systemic lupus erythematosus (SLE) and our advanced ISS technology using TLR9 agonists as vaccine adjuvants. Services and license revenue of \$2.4 million for the year ended December 31, 2008, was derived primarily from royalties received from customers of Dynavax Europe.

**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 2008 to 2009		Increase (Decrease) from 2007 to 2008	
	2009	2008	2007	\$	%	\$	%
Compensation and related personnel costs	\$ 15,601	\$ 18,020	\$ 19,170	\$ (2,419)	(13)%	\$ (1,150)	(6)%
Outside services	14,985	18,477	38,726	(3,492)	(19)%	(20,249)	(52)%
Facility costs	6,983	6,871	6,414	112	2%	457	7%
Impairment			444			(444)	(100)%
Non-cash stock-based compensation	1,139	1,403	1,134	(264)	(19)%	269	24%
Total research and development	\$ 38,708	\$ 44,771	\$ 65,888	\$ (6,063)	(14)%	\$ (21,117)	(32)%



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Research and development expenses for the year ended December 31, 2009 decreased by \$6.1 million, or 14%, compared to the same period in 2008. The decrease from fiscal 2008 was due primarily to a reduction in outside services resulted primarily from a reduction in clinical development costs associated with HEPLISAV and the discontinuation of clinical development for the TOLAMBA ragweed allergy program. We discontinued clinical development of TOLAMBA, our ragweed allergy product candidate, in May 2008. Compensation and related personnel costs decreased in 2009 due to a reduction in the number of employees engaged in research and development.

Research and development expenses for the year ended December 31, 2008 decreased by \$21.1 million, or 32%, compared to the same period in 2007. The decrease from fiscal 2007 was due primarily to a reduction in outside services which included a non-recurring \$5 million payment in June 2007 for a non-exclusive license to certain patents and patent applications for the purpose of commercializing HEPLISAV. The remaining decline in outside services resulted primarily from a reduction in clinical development costs associated with HEPLISAV and the discontinuation of clinical development for the TOLAMBA ragweed allergy program.

Research and development expenses in 2010 will depend in large part on our spending associated with the ongoing clinical trials for HEPLISAV, which will not be able to continue unless we raise significant additional funds in the near term. While we are actively seeking financing alternatives, we cannot assure that sufficient funding will be available on terms acceptable to us. If adequate funds are not available in the near term, we have developed contingency plans that would require us to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

**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):

	Years Ended December 31,			Increase (Decrease) from 2008 to 2009		Increase (Decrease) from 2007 to 2008	
	2009	2008	2007	\$	%	\$	%
<b>General and Administrative:</b>							
Compensation and related personnel costs	\$ 5,886	\$ 6,810	\$ 7,101	\$ (924)	(14)%	\$ (291)	(4)%
Outside services	4,033	4,209	5,248	(176)	(4)%	(1,039)	(20)%
Legal costs	3,003	1,696	2,951	1,307	77%	(1,255)	(43)%
Facility costs	927	946	596	(19)	(2)%	350	59%
Non-cash stock-based compensation	1,896	1,802	2,397	94	5%	(595)	(25)%
Total general and administrative	\$ 15,745	\$ 15,463	\$ 18,293	\$ 282	2%	\$ (2,830)	(15)%

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 and partially offset by a decrease in compensation and related personnel costs. The decrease in compensation and related personnel costs for 2009 is due to a reduction in the number of administrative employees providing organizational support.

General and administrative expenses for the year ended December 31, 2008 decreased by \$2.8 million, or 15%, compared to the same period in 2007. The decrease is primarily due to a reduction in legal costs related to patent activities. Outside services decreased in 2008 due to the decline in consulting and other professional fees incurred in conjunction with various corporate activities.



**Table of Contents*****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 5 years from the date of acquisition. Amortization of intangible assets was \$1.0 million for all three years ended December 31, 2009, 2008 and 2007, respectively.

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

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 translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. Interest expense includes amortization of deferred transaction costs and commitment fees related to the Deerfield financing agreement. The following is a summary of our interest and other income, loan forgiveness and interest expense (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2008 to 2009		Increase (Decrease) from 2007 to 2008	
	2009	2008	2007	\$	%	\$	%
Interest and other income	\$ 112	\$ 1,741	\$ 4,165	\$ (1,629)	(94)%	\$ (2,424)	(58)%
Loan forgiveness	\$	\$ 5,000	\$	\$ (5,000)	(100)%	\$ 5,000	100%
Interest expense	\$ (124)	\$ (9,157)	\$ (1,719)	\$ (9,033)	(99)%	\$ 7,438	433%

Interest and other income for the year ended December 31, 2009 decreased by \$1.6 million, or 94%, compared to the same period in 2008 due primarily to lower investment balances and the decline in returns on our investment portfolio resulting from current market conditions.

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

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

Pursuant to the agreements that we entered into with SDI in April 2006 and accounted for as variable interest entities, or VIEs, 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 interest in SDI. For the fiscal years ended December 31, 2009, 2008 and 2007, the loss attributed to the noncontrolling interest was \$4.2 million, \$5.7 million, and \$8.7 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 its 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 Dynavax, increasing net loss per share attributable to Dynavax common stockholders by \$19.7 million for the year ended December 31, 2009.

**Recent Accounting Pronouncements*****Accounting Standards Codification Topic No. 810 ( ASC 810 )***

ASC 810 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income (loss) attributable to the parent and to the

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noncontrolling interests, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. ASC 810 requires that the noncontrolling interest continue to be attributed its share of losses even if that attribution results in a deficit noncontrolling interest balance. ASC 810 also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. In addition, consolidated net loss has been adjusted to include the net loss attributed to the noncontrolling interest in SDI and consolidated comprehensive income or loss has been adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

On January 1, 2009, we adopted these provisions of and reporting standards of ASC 810 and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI was reclassified to equity.

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

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

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

Had the previous requirements been applied, the consolidated net loss attributable to Dynavax Technologies Corporation's common stockholders would have increased by \$1.9 million and the loss per share attributable to Dynavax common stockholders would have increased by \$0.05, for the year ended December 31, 2009.

***Accounting Standards Codification Topic No. 855 ( ASC 855 )***

ASC 855 establishes principles and requirements for the evaluation, recognition and disclosure of subsequent events. In particular, this topic sets forth: (i) the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, (ii) the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements and (iii) the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. Our adoption of ASC 855 in the year ended December 31, 2009 did not have an impact on its financial position or results of operations.

***Accounting Standards Update 2009-05***

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, *Measuring Liabilities at Fair Value* ( ASU 2009-05 ). This update provides amendments to Accounting Standards Codification Topic 820, *Fair Value Measurements and Disclosure* for the fair value measurement of liabilities ( ASC 820 ). ASU 2009-05 states that in the absence of a market for a liability a company can use: (i) the quoted price of the identical liability when traded as an asset, (ii) a quoted price for similar liabilities or similar liabilities when traded as assets; or (iii) another valuation technique that is consistent with the principles of ASC 820 such as a present value technique. ASU 2009-05 was adopted on October 1, 2009 and did not have a material impact on our financial position, results of operations or cash flows.

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

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition



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accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Dynavax means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. 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, 2009, we had \$36.7 million in cash and cash equivalents. Our funds are currently invested in highly liquid institutional money market funds.

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 operating activities during the year ended December 31, 2008 was \$17.0 million compared to \$32.0 million for the same period in 2007. The decrease in cash usage was due primarily to the reduction in our net loss for 2008 resulting from the increase in revenues, in particular, revenue associated with the Merck collaboration for HEPLISAV.

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 lower net proceeds from maturities of marketable securities. Cash provided by investing activities during the year ended December 31, 2008 was \$30.1 million compared to cash used of \$3.6 million for the same period in 2007. The increase in cash provided was primarily attributed to higher net proceeds from maturities of marketable securities.

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 the sales of our common stock under an equity distribution agreement entered into with Wedbush Morgan Securities ( Wedbush ) on August 17, 2009. Cash provided by financing activities during the year ended December 31, 2008 was \$1.4 million compared to \$35.7 million for the same period in 2007. Cash provided by financing activities primarily included \$2 million in loan proceeds from Deerfield, offset by a \$0.8 million cash repayment to Deerfield upon termination of the loan agreement.

In order to continue development of our product candidates, particularly HEPLISAV, we will have to raise significant additional funds in the near term. 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.

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We are engaged in active and ongoing discussions to pursue additional capital through a combination of public and private equity offerings and strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources.

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 on hand at December 31, 2009, anticipated revenues, reductions in our current spending levels, and the successful completion of ongoing financing activities. Our failure to raise capital in the near term or to timely reduce costs could shorten this period.

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 near term, we have developed contingency plans that would require us to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

Our independent registered public accounting firm has included in their audit opinion for the year ended December 31, 2009 a statement with respect to our ability to continue as a going concern. However, 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. The reaction of investors to the inclusion of a going concern statement by our auditors, our lack of cash resources, and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into strategic alliances.

**Contractual Obligations**

The following summarizes our significant contractual obligations as of December 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More Than 5 Years</b>
Future minimum payments under our operating leases, excluding payments from the sublease agreement	\$ 17,994	\$ 2,629	\$ 8,221	\$ 2,658	\$ 4,486
Long-term note payable to Symphony Dynamo Holdings	15,000		15,000		
<b>Total</b>	<b>\$ 32,994</b>	<b>\$ 2,629</b>	<b>\$ 23,221</b>	<b>\$ 2,658</b>	<b>\$ 4,486</b>

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

As part of the consideration transferred from Dynavax to Holdings for the acquisition of SDI, the Company is 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 \$3.0 million as of December 31, 2009.

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

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of December 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of December 31, 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, 2009, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$15.5 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. As of December 31, 2009, we estimate that such fees to the Regents could approximate \$0.3 million during 2010.

### ***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 variable interest entity 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

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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 U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2009 was \$0.2 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
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**Report of Independent Registered Public Accounting Firm**

To The Board of Directors and Stockholders

Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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 and cash and cash equivalents balance at December 31, 2009 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 2009 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Also, as discussed in Note 2 to the consolidated financial statements, the Company retrospectively changed its method of accounting for and presentation of its noncontrolling interest as required by the issuance of authoritative accounting pronouncements.

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, 2009, 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 15, 2010, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Francisco, California

March 15, 2010

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

	December 31,	
	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,720	\$ 28,103
Marketable securities		15,264
Investments held by Symphony Dynamo, Inc. (SDI)		25,109
Restricted cash	681	668
Accounts receivable	895	6,407
Prepaid expenses and other current assets	586	991
<b>Total current assets</b>	<b>38,882</b>	<b>76,542</b>
Property and equipment, net	7,997	9,510
Goodwill	2,312	2,312
Other intangible assets, net	1,279	2,259
<b>Total assets</b>	<b>\$ 50,470</b>	<b>\$ 90,623</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,686	\$ 905
Accrued liabilities	7,507	6,816
Deferred revenues	2,718	33,133
Warrant liability to Symphony Dynamo Holdings LLC (Holdings)	2,567	
<b>Total current liabilities</b>	<b>14,478</b>	<b>40,854</b>
Deferred revenues, noncurrent	17,083	18,512
Liability from program option exercised under the SDI collaboration		15,000
Long-term note payable to Holdings	9,342	
Long-term contingent liability to Holdings	3,040	
Other long-term liabilities	151	101
Commitments and contingencies (Note 10)		
Dynavax stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2009 and 2008		
Common stock: \$0.001 par value; 150,000 and 100,000 shares authorized at December 31, 2009 and 2008, respectively; 54,279 and 39,854 shares issued and outstanding at December 31, 2009 and 2008, respectively	54	40
Additional paid-in capital	266,127	262,579
Accumulated other comprehensive income (loss):		
Unrealized gain on marketable securities available-for-sale		49
Cumulative translation adjustment	(168)	(403)
<b>Accumulated other comprehensive income (loss)</b>	<b>(168)</b>	<b>(354)</b>
<b>Accumulated deficit</b>	<b>(259,637)</b>	<b>(248,743)</b>
<b>Total Dynavax stockholders' equity</b>	<b>6,376</b>	<b>13,522</b>
Noncontrolling interest in SDI		2,634

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Total stockholders' equity	6,376	16,156
Total liabilities and stockholders' equity	\$ 50,470	\$ 90,623

*See accompanying notes.*

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

(In thousands, except per share amounts)

	Years Ended December 31,		
	2009	2008	2007
<b>Revenues:</b>			
Collaboration revenue	\$ 35,534	\$ 31,666	\$ 9,315
Grant revenue	3,477	2,999	3,046
Service and license revenue	1,307	2,429	1,732
<b>Total revenues</b>	<b>40,318</b>	<b>37,094</b>	<b>14,093</b>
<b>Operating expenses:</b>			
Research and development	38,708	44,771	65,888
General and administrative	15,745	15,463	18,293
Amortization of intangible assets	980	980	1,004
<b>Total operating expenses</b>	<b>55,433</b>	<b>61,214</b>	<b>85,185</b>
<b>Loss from operations</b>	<b>(15,115)</b>	<b>(24,120)</b>	<b>(71,092)</b>
Interest and other income	112	1,741	4,165
Loan forgiveness		5,000	
Interest expense	(124)	(9,157)	(1,719)
<b>Net loss</b>	<b>(15,127)</b>	<b>(26,536)</b>	<b>(68,646)</b>
Consideration paid in excess of carrying value of the noncontrolling interest in SDI	(19,671)		
<b>Add: Losses attributable to noncontrolling interest in SDI</b>	<b>4,233</b>	<b>5,707</b>	<b>8,675</b>
<b>Net loss attributable to Dynavax</b>	<b>\$ (30,565)</b>	<b>\$ (20,829)</b>	<b>\$ (59,971)</b>
<b>Basic and diluted net loss per share attributable to Dynavax common stockholders</b>	<b>\$ (0.76)</b>	<b>\$ (0.52)</b>	<b>\$ (1.51)</b>
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	40,350	39,819	39,746

*See accompanying notes.*

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

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Total Dynavax Stockholders Equity	Noncontrolling Interest in SDI	Total Stockholders Equity
	Shares	Par Amount		Income	Accumulated Deficit			
Balances at December 31, 2006	39,715	\$ 40	\$ 244,787	\$ 172	\$ (167,943)	\$ 77,056	\$ 2,016	\$ 79,072
Exercise of stock options	6		22			22		22
Issuance of common stock under Employee Stock Purchase Plan	44		149			149		149
Proceeds from issuance of common stock, net of fees			(19)			(19)		(19)
Proceeds from the purchase of noncontrolling interest by the shareholders in SDI, net of fees							30,000	30,000
Liability from program option exercise							(15,000)	(15,000)
Issuance of warrants in conjunction with Deerfield financing agreement			9,796			9,796		9,796
Stock compensation expense			3,531			3,531		3,531
Comprehensive loss:								
Change in unrealized gain on marketable securities				110		110		110
Cumulative translation adjustment				116		116		116
Net loss					(59,971)	(59,971)	(8,675)	(68,646)
Comprehensive loss						(59,745)	(8,675)	(69,488)
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)
Comprehensive loss						(21,581)	(5,707)	(21,581)
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)

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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)
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

*See accompanying notes.*

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

(In thousands)

	Years Ended December 31,		
	2009	2008	2007
<b>Operating activities</b>			
Net loss attributable to Dynavax	\$ (30,565)	\$ (20,829)	\$ (59,971)
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)	(8,675)
Depreciation and amortization	1,857	1,850	1,483
Amortization of intangible assets	980	980	1,004
(Gain) loss on disposal of property and equipment	12	32	
Accretion and amortization on marketable securities	4	(721)	(1,855)
Interest associated with Deerfield financing agreement	84	9,090	1,248
Loan forgiveness		(5,000)	
Stock-based compensation expense	3,035	3,205	3,531
Changes in operating assets and liabilities:			
Accounts receivable	5,512	827	(5,080)
Prepaid expenses and other current assets	405	1,533	(1,851)
Inventory			257
Other assets	(13)	(79)	1,269
Accounts payable	781	(3,513)	2,237
Accrued liabilities	762	(6,129)	930
Deferred revenues	(31,844)	7,426	33,441
Net cash used in operating activities	(33,552)	(17,035)	(32,032)
<b>Investing activities</b>			
Change in investments held by SDI	5,041	6,522	(18,268)
Purchases of marketable securities	(14,289)	(35,755)	(80,232)
Proceeds from maturities of marketable securities	29,500	59,401	98,550
Proceeds from sales of marketable securities		4,046	
Purchases of property and equipment	(377)	(4,098)	(3,647)
Net cash provided by (used in) investing activities	19,875	30,116	(3,597)
<b>Financing activities</b>			
Proceeds from purchase of noncontrolling interest by preferred shareholders in SDI, net of fees			30,000
Cash acquired from the purchase of noncontrolling interest in SDI	19,732		
Proceeds from notes payable issued to Deerfield		2,000	5,500
Repayment of notes payable issued to Deerfield		(817)	
Proceeds from issuance of common stock, net of issuance costs	2,242		(19)
Proceeds from exercise of stock options	13	5	22
Proceeds from employee stock purchase plan	72	204	149
Net cash provided by financing activities	22,059	1,392	35,652
Effect of exchange rate on cash and cash equivalents	235	(663)	116
Net increase in cash and cash equivalents	8,617	13,810	139
Cash and cash equivalents at beginning of year	28,103	14,293	14,154
Cash and cash equivalents at end of year	\$ 36,720	\$ 28,103	\$ 14,293

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### Supplemental disclosure of cash flow information

Cash paid during the year for interest	\$	\$ 885	\$ 356
Non-cash activities:			
Note payable to Holdings from purchase option exercised under the SDI collaboration	\$ 9,342	\$	\$
Shares issued in conjunction with the SDI transaction	\$ 18,590	\$	\$
Liability from program option exercised under the SDI collaboration	\$ (15,000)	\$	\$ 15,000
Warrants issued in conjunction with the SDI transaction	\$ 1,764	\$	\$
Warrants issued in conjunction with the Deerfield financing agreement	\$	\$	\$ 9,796
Loan forgiveness	\$	\$ 5,000	\$
Modification of warrants previously issued to Deerfield	\$ 84	\$ 899	\$
Disposal of fully depreciated property and equipment	\$ 1,215	\$	\$ 238

*See accompanying notes.*



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**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 diseases, asthma and inflammatory and autoimmune diseases. Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs including those partnered with AstraZeneca and GlaxoSmithKline ( GSK ) and our Universal Flu vaccine. 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. We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

**Subsidiaries**

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries. On December 30, 2009, Dynavax acquired all of the outstanding equity of Symphony Dynamo, Inc. (SDI) (see Note 8). Prior to December 30, 2009, Dynavax consolidated the financial results of SDI, as Dynavax was deemed a variable interest entity and Dynavax was 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 2009, 2008 and 2007, respectively, 97%, 93% and 88% of our revenues were earned in the U.S. and the remaining revenues were earned in Europe. As of December 31, 2009 and 2008, respectively, 43% and 48% of our long-lived assets were located in the U.S. and the remaining assets were located in Europe.

**Liquidity and Financial Condition**

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2009, we had cash and cash equivalents of \$36.7 million, restricted cash of \$0.7 million and working capital of \$24.4 million. We currently estimate that we will have sufficient cash resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents on hand at December 31, 2009, anticipated revenues, reductions in our current spending levels, and the successful completion of ongoing financing activities.

In order to continue development of our product candidates, particularly HEPLISAV, we will have to raise significant additional funds in the near term. We are engaged in active and ongoing discussions to pursue additional capital through a combination of public and private equity offerings and strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources. 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

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available in the near term, we have developed contingency plans that would require us to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

The accompanying financial statements have been prepared assuming the Company 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 the Company's ability to continue as a going concern.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 subsidiaries. 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. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2009 was \$0.2 million. Gains and losses resulting from currency transactions are included in the consolidated statements of operations. We reported a \$54 thousand loss resulting from currency translations in our consolidated statement of operations for the year ended December 31, 2009.

### **Cash, Cash Equivalents, Marketable Securities and Investments held by SDI**

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 quoted market prices, with unrealized gains and losses included in accumulated other comprehensive income in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

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

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

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

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



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### **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, accounts receivable, and marketable securities. 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 consolidated financial position and results of operations.

We rely on a single contract manufacturer to produce material for certain of our clinical trials. The loss of our current supplier could delay development or commercialization of our product candidates. To date, we have manufactured only small quantities of material for research 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 the Berkeley facility have estimated useful lives of three years for computer equipment and furniture, and five years for laboratory equipment. The assets in the 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;

significant negative industry or economic trends;



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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 exceeds the projected discounted future net cash flows associated with the assets. For the years ended December 31, 2009 and 2008, we recognized no impairment charge as it relates to our long-lived assets. For the year ended December 31, 2007, we recognized an impairment charge included in research and development expenses of \$0.4 million to write off the carrying amount of the intangible asset related to the Supravax developed technology acquired as part of the Rhein Biotech GmbH acquisition and related inventory (See Note 6).

### **Revenue Recognition**

Our revenues are derived from collaborative 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. Advance payments received in excess of amounts earned are classified as deferred revenue until earned. 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.

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

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and administrative cost rate reimbursable per the terms of the grant awards. Any amounts received in advance of performance are recorded as deferred revenue until earned.

### **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 and Other Intangible Assets**

Goodwill amounts are 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 valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. 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, or 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

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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 Symphony Dynamo, Inc., a variable interest entity, of which we were the primary beneficiary (refer to Note 8 below).

### **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 forfeiture rate, 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 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 year ended December 31, 2009. 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.

Effective January 1, 2007, we adopted the provisions for accounting for uncertainty in income taxes, which specifies how tax benefits for uncertain tax positions are to be recognized, measured and derecognized in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim-period guidance, among other provisions.

At the date of adoption, there was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of December 31, 2009, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. income taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2010.

### **Recent Accounting Pronouncements**

#### ***Accounting Standards Codification Topic No. 810 ( ASC 810 )***

ASC 810 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income (loss) attributable to the parent and to the



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noncontrolling interests, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. ASC 810 requires that the noncontrolling interest continue to be attributed its share of losses even if that attribution results in a deficit noncontrolling interest balance. ASC 810 also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. In addition, consolidated net loss has been adjusted to include the net loss attributed to the noncontrolling interest in SDI and consolidated comprehensive income or loss has been adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

On January 1, 2009, we adopted these provisions of and reporting standards of ASC 810 and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI was reclassified to equity.

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

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

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

Had the previous requirements been applied, the consolidated net loss attributable to Dynavax Technologies Corporation's common stockholders would have increased by \$1.9 million and the loss per share attributable to Dynavax common stockholders would have increased by \$0.05, for the year ended December 31, 2009.

***Accounting Standards Codification Topic No. 855 ( ASC 855 )***

In May 2009, ASC 855 establishes principles and requirements for the evaluation, recognition and disclosure of subsequent events. In particular, this topic sets forth: (i) the period after the balance sheet date during which management of a reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, (ii) the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements and (iii) the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. Our adoption of ASC 855 in the year ended December 31, 2009 did not have an impact on its financial position or results of operations.

***Accounting Standards Update 2009-05***

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, *Measuring Liabilities at Fair Value* ( ASU 2009-05 ). This update provides amendments to Accounting Standards Codification Topic 820, *Fair Value Measurements and Disclosure* for the fair value measurement of liabilities ( ASC 820 ). ASU 2009-05 states that in the absence of a market for a liability a company can use: (i) the quoted price of the identical liability when traded as an asset, (ii) a quoted price for similar liabilities or similar liabilities when traded as assets; or (iii) another valuation technique that is consistent with the principles of ASC 820 such as a present value technique. ASU 2009-05 was adopted on October 1, 2009 and did not have a material impact on our financial position, results of operations or cash flows.

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

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition



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accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Dynavax means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. 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.

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and investments held by SDI measured at fair value on a recurring basis as of years ended December 31, 2009 and 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
<b>December 31, 2009</b>				
<b>Assets</b>				
Money market funds	\$ 33,788	\$	\$	\$ 33,788
Total assets	\$ 33,788	\$	\$	\$ 33,788
<b>Liabilities</b>				
Warrant liability	\$	\$	\$ 2,567	\$ 2,567
Long-term note payable to Symphony Dynamo Holdings LLC ( Holdings )			9,342	9,342
Long-term contingent consideration liability to Holdings			3,040	3,040
Total Liabilities	\$	\$	\$ 14,949	\$ 14,949



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	Level 1	Level 2	Level 3	Total
<b>December 31, 2008</b>				
Money market funds	\$ 43,773	\$	\$	\$ 43,773
U.S. Government agency securities		12,774		12,774
FDIC insured corporate debt securities		3,749		3,749
Corporate debt securities		2,500		2,500
Total	\$ 43,773	\$ 19,023	\$	\$ 62,796

**Assets**

The Company had zero and \$4.0 million sales of marketable securities during the years ended December 31, 2009 and 2008, respectively. As of December 31, 2009, the Company had no marketable securities.

When determining if there are any other-than-temporary impairments on its investments, the Company evaluates: (i) whether the investment has been in a continuous realized loss position for over twelve months, (ii) the duration to maturity of the Company's investments, (iii) the Company's 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, 2009, the Company has not recognized any other-than-temporary losses on its investments.

**Liabilities**

In connection with the exercise of the Company's purchase of all of the outstanding equity of SDI, the Company issued the following components of consideration which were accounted for as liabilities on the consolidated balance sheet as of December 31, 2009 (in thousands):

Description	Amount
Warrant consideration	\$ 2,567
Note payable to Holdings	9,342
Contingent consideration liability to Holdings	3,040
Balance as of December 31, 2009	\$ 14,949

The Company issued warrants to Symphony which contained provisions for anti-dilution protection in the event that the Company issues other equity securities within six months from the closing date of the transaction. Due to this adjustment provision, the warrants do not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock. Accordingly, the Company has recorded these warrants as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. This fair value measurement is 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 the Company's assumptions in measuring fair value.

In connection with the acquisition of SDI, the Company entered into a \$15 million non-interest bearing note payable in full on December 31, 2012. 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 solely in shares of our common stock, the number of shares issued will be determined by our stock price at the date of payment. This fair value measurement is 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 the Company's assumptions in measuring fair value.

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The Company is also obligated to make future contingent cash payments to the former Holdings shareholders related to certain payments received by the Company from future partnering agreements pertaining to its hepatitis C and cancer therapy programs (see Note 8). The Company 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 an 18% rate. This fair value measurement is 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 the Company's assumptions in measuring fair value.

The Company assumed these liabilities at December 30, 2009 and determined that the adjustment to the fair value measurement for the period ending December 31, 2009 was not material.

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

The following is a summary of available-for-sale securities included in cash and cash equivalents, marketable securities, investments held by SDI and restricted cash as of December 31, 2009 and 2008 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>December 31, 2009:</b>				
Certificates of deposit and money market funds	\$ 34,634	\$	\$	\$ 34,634
<b>Total</b>	<b>\$ 34,634</b>	<b>\$</b>	<b>\$</b>	<b>\$ 34,634</b>
<b>December 31, 2008:</b>				
Certificates of deposit and money market funds	\$ 44,498	\$	\$	\$ 44,498
U.S. Government agency securities	12,743	31		12,774
FDIC insured corporate debt securities	3,736	13		3,749
Corporate debt securities	2,495	5		2,500
<b>Total</b>	<b>\$ 63,472</b>	<b>\$ 49</b>	<b>\$</b>	<b>\$ 63,521</b>

There were zero realized gains from the sale of marketable securities for the year ended December 31, 2009, and immaterial realized gain for the year ended December 31, 2008 and no realized gain for the year ended December 31, 2007. Realized losses from the sale of marketable securities were zero in 2009, 2008 and 2007. As of December 31, 2009, we had zero marketable securities. As of December 31, 2008, 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.

**Table of Contents****5. Property and Equipment**

Property and equipment as of December 31, 2009 and 2008 consist of the following (in thousands):

	December 31,	
	2009	2008
Laboratory equipment	\$ 14,937	\$ 15,433
Computer equipment	1,331	1,461
Furniture and fixtures	1,581	1,810
Leasehold improvements	3,734	3,593
	21,583	22,297
Less accumulated depreciation and amortization	(13,586)	(12,787)
<b>Total</b>	<b>\$ 7,997</b>	<b>\$ 9,510</b>

Depreciation and amortization expense on property and equipment was \$1.9 million, \$1.9 million and \$1.5 million for the years ended December 31, 2009, 2008, and 2007, respectively.

**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 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, 2009 and December 31, 2008 (in thousands, except years):

	Estimated Useful Life (In years)	December 31, 2009			December 31, 2008		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
<b>Intangible Assets:</b>							
Manufacturing process	5	\$ 3,670	\$ (2,712)	\$ 958	\$ 3,670	\$ (1,978)	\$ 1,692
Customer relationships	5	1,230	(909)	321	1,230	(663)	567
Total		\$ 4,900	\$ (3,621)	\$ 1,279	\$ 4,900	\$ (2,641)	\$ 2,259

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

Year ending December 31,	
2010	\$ 980
2011	299
Total	\$ 1,279

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 which are listed in Note 1. 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, 2009 and 2008, we recognized no impairment charge as it relates to our intangible assets.



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For the year ended December 31, 2007, we recognized an impairment charge included in research and development expenses of \$0.4 million to write off the carrying amount of the intangible asset related to developed technology acquired as part of the Rhein Biotech GmbH acquisition and related inventory.

**7. Current Accrued Liabilities**

Current accrued liabilities as of December 31, 2009 and 2008 consist of the following (in thousands):

	December 31,	
	2009	2008
Payroll and related expenses	\$ 2,521	\$ 2,419
Legal expenses	1,140	1,387
Third party scientific research expense	2,155	1,730
Other accrued liabilities	1,691	1,280
<b>Total</b>	<b>\$ 7,507</b>	<b>\$ 6,816</b>

**8. Symphony Dynamo, Inc.**

On April 18, 2006, we, Symphony and Holdings entered into a transaction involving a series of related agreements providing for the advancement of specific Dynavax immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the Programs). Pursuant to these agreements, Symphony and certain of its affiliates formed Symphony Dynamo Inc. (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 owns 100% of the equity of Holdings, which owns 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). The Original Purchase Option would have been exercisable for a price of \$106.9 million as of October 1, 2009, which purchase price would have increased quarterly by a predetermined amount up to \$144.1 million if the Original Purchase Option were exercised on April 18, 2011. If not exercised, the Original Purchase Option would have expired on April 18, 2011. The exercise price of the Original Purchase Option could have been paid for in cash or a combination of cash and our common stock. 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 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 have 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 have agreed to with Holdings.

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.

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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 have consolidated the financial position and results of operations of SDI. We have not consolidated Holdings because we believe our variable interest, the Purchase Option, is on the stock of SDI. We believe SDI is a VIE because we have 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.

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 are 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 are 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.

Symphony was required to absorb the development risk for its equity investment in SDI. Symphony's equity investment in SDI was classified as noncontrolling interest in the consolidated balance sheet. The noncontrolling interest held by Symphony has been 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.

Net losses incurred by SDI and charged to the noncontrolling interest were \$4.2 million, \$5.7 million and \$8.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

In December 2007, the FASB 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 net loss attributable to Dynavax would have increased by \$1.9 million and the loss per share attributable to Dynavax common stockholders would have increased by \$0.05 for 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 purchase option. We completed the acquisition of all of the outstanding equity of SDI pursuant to the amended purchase option on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to the Symphony Investors: (i) 13 million shares of common stock (Shares); (ii) 5 year warrants to purchase 2 million shares of common stock with an exercise price of \$1.94 per share (Warrants); (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; and

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(iv) 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. The outstanding warrants to purchase 2 million shares of common stock held by the Symphony Investors were cancelled. The Shares and Warrants are subject to certain anti-dilution protection in the event that the Company issues other equity securities within six months from the closing date of the transaction. Due to this adjustment provision, the warrants do not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock. Accordingly, the Company has recorded these warrants as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. The warrants will be revalued every reporting period using the Black-Scholes Model and the change in the fair value of the warrants will be recognized in the other income (expense) line item in the Company's consolidated statement of operations.

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 net loss. However, because the acquisition was accounted for as a capital transaction, the excess consideration transferred over the carrying value of the noncontrolling and is treated as a deemed dividend for purposes of reporting net loss and earnings per share, increasing net loss attributable to Dynavax and loss per share attributable to Dynavax common stockholders for the year ended December 31, 2009.

The following table outlines the estimated fair value of consideration transferred by us and the computation of the excess consideration transferred over the carrying value of the noncontrolling interest in SDI (in thousands):

Description	Fair Value
Fair value of consideration transferred:	
13,000,000 shares of Dynavax common stock	\$ 18,590
Warrant consideration	2,567
Note payable to Holdings	9,342
Contingent consideration liability for future cash payments to Holdings	3,040
 Total consideration transferred	 33,539
 Less: Fair value of cancelled warrants	 (802)
Less: Cancellation of program option liability	(15,000)
Add: Deficit of noncontrolling interest in SDI	1,934
 Consideration paid in excess of carrying value of the noncontrolling interest in SDI	 \$ 19,671

The fair value of the Dynavax common stock 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 warrant consideration were calculated using the Black-Scholes valuation model, and the following weighted average assumptions:

	Warrant Issued	Warrant Cancelled
Number of Shares	2,000,000	2,000,000
Expected term	5.0 years	1.3 years
Expected volatility	150%	150%
Risk-free interest rate	2.61%	0.45%
Dividend yield	0%	0%

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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 solely in shares of our common stock, the number of shares issued will be determined by our stock price at the date of payment with a 15% premium for the portion repaid in shares.

We estimated the fair value of the contingent consideration 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 an 18% rate.

Changes in the fair value of the acquisition-related contingent consideration liability subsequent to the December 30, 2009 acquisition date will be 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.

## **9. Financing Agreements**

On August 17, 2009 the Company entered into an equity distribution agreement (the "Agreement") with Wedbush Morgan Securities, Inc. ("Wedbush") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the quarter ended September 30, 2009, we sold 1,281,100 shares of common stock under the Agreement with Wedbush as our sales agent for aggregate net proceeds of \$2.3 million after deducting commissions paid to Wedbush and offering expenses. As of December 31, 2009, we could offer and sell from time to time through Wedbush up to an additional \$12.2 million in aggregate offering price of our common stock under the Agreement.

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

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

Under the Loan Agreement, through August 26, 2008 (the date of termination), we had received \$7.5 million in cash from Deerfield, which was recorded as a long-term liability in our consolidated balance sheet. Additionally, we paid and recognized as interest expense \$1.7 million of commitment fees and we issued to Deerfield warrants to purchase up to 3,550,000 shares of our common stock. The warrants were valued on the

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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	Black-Scholes Assumptions		Exercise Price per Share	Assigned Value using Black-Scholes
			Expected Life (in years)	Volatility		
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
<b>Total</b>	<b>3,550</b>					<b>\$ 9,796</b>

At the date of each issuance, the warrant valuation was recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost was amortized on a straight-line basis and recognized as interest expense through the termination of the Loan Agreement. We amortized zero and \$9.0 million of deferred transaction cost in interest expense for the years ended December 31, 2009 and 2008, respectively.

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

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
<b>Total</b>	<b>3,550</b>		

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

The amendments to the warrants resulted in a re-measurement of the fair value based on the amended terms and current period assumptions and were accounted for as modifications to equity awards under the provisions of Topic 718, *Compensation-Stock Compensation*. We recorded interest expense and an increase of additional paid in capital of \$0.1 million and \$0.9 million for the years ended December 31, 2009 and 2008, respectively due to these modifications.

**10. Commitments and Contingencies**

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and March 2023, respectively. The



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Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of December 31, 2009 and December 31, 2008. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2014. Total net rent expense related to our operating leases for the years ended December 31, 2009, 2008 and 2007, was \$2.5 million, \$2.5 million and \$2.1 million, respectively. Deferred rent was \$0.9 million as of December 31, 2009.

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

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2009, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2010	\$ 2,629
2011	2,686
2012	2,745
2013	2,790
2014	2,039
Thereafter	5,105
 Total	 \$ 17,994

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

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of December 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of December 31, 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, 2009, under the terms of our agreements, we are obligated to make future

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payments as services are provided of approximately \$15.5 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Under the terms of our license agreements, we could be expected to pay approximately \$0.3 million in 2010 related to such fees and milestone payments to the Regents.

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

#### **GlaxoSmithKline**

In December 2008, we entered into a worldwide strategic alliance with GlaxoSmithKline ( GSK ) to discover, develop, and commercialize toll-like receptor ( TLR ) inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We received an initial payment of \$10 million and agreed to conduct research and early clinical development in up to four programs and are eligible to receive future potential development and commercialization milestones. 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, 2009 and 2008, we recognized revenue of \$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 with our prior consent. We have the option to co-promote in the United States products arising from the collaboration. We received an upfront payment of \$10 million, and are eligible to receive research funding, preclinical milestone payments, and potential future development milestones. Upon commercialization, we are also eligible to receive royalties based on product sales.

In September 2008, we received a \$4.5 million milestone payment from AstraZeneca for the nomination of a candidate drug. Revenue from milestones received during the development plan is deferred and recognized ratably over estimated performance period of the collaboration agreement. For the years ended December 31, 2009 and 2008, we recognized revenue of \$1.7 million and \$2.0 million, respectively, related to the milestone for the nomination of a candidate drug. Collaboration revenue resulting from the performance of research services amounted to \$3.4 million and \$3.2 million for the years ended December 31, 2009, and 2008, respectively. As of December 31, 2009, we recorded deferred revenue of \$11 million associated with the milestone for the nomination of a candidate drug, upfront fee and amounts billed in advance for research services per the contract terms.

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

In September 2008, we were awarded a five-year \$17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the NIH's National Institute of Allergy and



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Infectious Diseases (NIAID) to develop novel vaccine adjuvant candidates that signal through receptors of the innate immune system. The contract supports adjuvant development for anthrax as well as other disease models. NIAID is funding 100% of the total \$17 million cost of Dynavax's program under Contract No. HHSN272200800038C. For the years ended December 31, 2009 and 2008, we recognized revenue of approximately \$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 (SLE), an autoimmune disease. Revenue associated with this grant is recognized as the related expenses are incurred. For the years ended December 31, 2009 and 2008, we recognized revenue of approximately \$0.9 million and \$0.4 million respectively.

In 2004, we were awarded \$0.5 million from the Alliance for Lupus Research to fund research and development of new treatment approaches for lupus. We recognized revenue associated with the lupus grant of approximately \$0.1 million for the year ended December 31, 2007 and 2006.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the second quarter of 2009. In August 2007, we were awarded a two-year \$3.3 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with these grants is recognized as the related expenses are incurred. For years ended December 31, 2009, 2008 and 2007, we recognized revenue of approximately \$3.5 million, \$3.0 million and \$3.0 million, respectively.

### **Merck & Co., Inc.**

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

On December 18, 2008, Merck provided notice of its termination of the collaboration. As a result of the termination, all development, manufacturing and commercialization rights to HEPLISAV reverted to Dynavax. Merck is obligated to make certain mutually agreed-upon payments to Dynavax for the 180-day wind down period following Merck's written notice of termination. As a result of Merck's termination, we accelerated the applicable performance period over which we ratably recognize revenue from the upfront fee through the effective date of the termination, which is June 2009. For the years ended December 31, 2009 and 2008, we recognized revenue of \$28.5 million and \$5 million, respectively, related to the upfront fee. Collaboration revenue resulting from the performance of research and development services are recognized as related research and development costs are incurred. Cost reimbursement revenue under this collaboration agreement totaled \$0.3 million and \$20.2 million for the years ended December 31, 2009 and 2008, respectively. In the first quarter of 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.

**Table of Contents****12. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Years Ended December 31,		
	2009	2008	2007
<b>Historical (in thousands, except per share amounts):</b>			
Numerator:			
Net loss attributable to Dynavax	\$ (30,565)	\$ (20,829)	\$ (59,971)
Denominator for basic and diluted net loss per share attributable to Dynavax common stockholders :			
Weighted-average common shares outstanding	40,350	39,819	39,746
Basic and diluted net loss per share attributable to Dynavax common stockholders	\$ (0.76)	\$ (0.52)	\$ (1.51)
<b>Historical outstanding securities not included in diluted net loss per share calculation (in thousands):</b>			
Options to purchase common stock	5,561	5,173	4,282
Warrants	5,550	5,550	5,550
	11,111	10,723	9,832

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

As of December 31, 2009, 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; and the 2004 Employee Stock Purchase 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 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.

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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.

As of December 31, 2009, 5,500,000 shares have been reserved and approved for issuance under the Plan, subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure.

Activity under our stock plans is set forth below:

	Options and Awards Available for Grant	Number of Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2008	660,653	4,822,976	\$ 5.04
Options authorized	400,000		
Options granted	(1,398,350)	1,398,350	\$ 0.96
Restricted stock awards and units (Awards) granted			
Options exercised			
1997 Plan options exercised		(2,666)	\$ 1.50
Options cancelled:			
Options forfeited (unvested)	438,194	(438,194)	\$ 3.50
Options expired (vested)	498,412	(498,412)	\$ 6.56
1997 Plan options expired (vested)		(5,999)	\$ 6.56
Awards cancelled (unvested)	60,000		\$
Balance at December 31, 2009	658,909	5,276,055	\$ 3.94

During the fiscal year ended December 31, 2007, we granted a restricted stock award (RSA) for 5,000 shares with a grant date fair value of \$4.54 and vested 100% on the third anniversary of this vest commencement date. During the fiscal year ended December 31, 2009, this option vested in full and we released the 5,000 shares. The total intrinsic value of the RSA released during the years ended December 31, 2009 was \$9 thousand dollars. The Company did not have any RSAs released during the years ended December 31, 2008 and 2007.

In October 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 October 2008, the Company had no RSUs outstanding. There were 60,000 and 90,000 RSU shares forfeited during the fiscal year ended December 31, 2009 and 2008, respectively. There were 285,000 unvested RSU shares as of December 31, 2009. There were no vested RSU shares delivered during the years ended December 31, 2009 and 2008.

**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

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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, 2009, 496,000 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 330,107 shares of our common stock under the Purchase Plan. At December 31, 2009, 165,893 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 (the Record Date) 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 (the Purchase Price), 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 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 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 the 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.

**Employment Inducement Stock Award Plan**

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

**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 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		
	2009	2008	2007	2009	2008	2007
Weighted-average fair value	\$ 0.55	\$ 2.29	\$ 3.53	\$ 0.88	\$ 0.93	\$ 1.96
Risk-free interest rate	1.7%	2.7%	4.7%	0.7%	2.4%	4.6%
Expected life (in years)	4.0	4.4	4.5	1.1	1.3	1.2
Volatility	1.6	0.8	0.8	1.6	0.8	0.7

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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. 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 estimated fair value of restricted stock units awards is calculated based on the market price of Dynavax's common stock on the date of grant, reduced by the present value of dividends expected to be paid on Dynavax's common stock prior to vesting of the restricted stock unit. The Company's estimate assumes no dividends will be paid prior to the vesting of the restricted stock unit.

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

	Years Ended December 31,		
	2009	2008	2007
Employees and directors stock-based compensation expense	\$ 3,014	\$ 3,183	\$ 3,462
Non-employees stock-based compensation expense	21	22	69
<b>Total</b>	<b>\$ 3,035</b>	<b>\$ 3,205</b>	<b>\$ 3,531</b>

	Years Ended December 31,		
	2009	2008	2007
Research and development	\$ 1,139	\$ 1,403	\$ 1,134
General and administrative	1,896	1,802	2,397
<b>Total</b>	<b>\$ 3,035</b>	<b>\$ 3,205</b>	<b>\$ 3,531</b>

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized for the year ended December 31, 2009 was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 15% for both the executive level and non-executive level employee groups. As of December 31, 2009, the total unrecognized compensation cost related to non-vested options granted amounted to \$3.3 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.3 years. The Company did not issue any restricted stock units or awards during the year ended December 31, 2009. The weighted average purchase price of restricted stock units issued was zero during the year ended December 31, 2009.

Total options exercised during the years ended December 31, 2009, 2008 and 2007 were 2,666, 1,833 and 5,666, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2009, 2008 and 2007 was approximately \$1 thousand, \$6 thousand and \$6 thousand, respectively. Total restricted stock awards released during the year ended December 31, 2009 was 5,000. No income tax benefits have been realized by us in 2009, 2008 and 2007, as we reported a net loss in each year.

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, 2009:

	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)	4,858,937	\$ 4.05	6.4	\$ 718
Options exercisable	2,848,434	\$ 4.78	5.6	\$ 1



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We maintained 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**

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,		
	2009	2008	2007
U.S.	\$ (11,369)	\$ (19,265)	\$ (58,521)
Non U.S.	475	(1,564)	(1,450)
<b>Total</b>	<b>\$ (10,894)</b>	<b>\$ (20,829)</b>	<b>\$ (59,971)</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, 2009, 2008 and 2007 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,		
	2009	2008	2007
Income tax benefit at federal statutory rate	\$ (3,722)	\$ (7,082)	\$ (20,390)
State tax	(1,727)	(1,601)	(2,600)
Tax credits	(1,473)	(672)	(2,594)
Deferred compensation charges	439	503	495
Change in valuation allowance	6,873	13,792	20,680
Change in foreign tax rates	427		1,966
Change in NOL	(1,439)	(4,810)	2,356
Limitation of NOLs	628		
Other	(6)	(130)	87
	\$	\$	\$

Deferred tax assets and liabilities as of December 31, 2009 and 2008 consist of the following (in thousands):

	December 31,	
	2009	2008
<b>Deferred tax assets:</b>		
Net operating loss carry forwards	\$ 68,641	\$ 64,967
Research tax credit carry forwards	13,005	10,517
Accruals and reserves	4,653	3,483
Capitalized research costs	14,208	8,108
Deferred Revenue	7,373	14,788
Other	2,914	2,431
	110,794	104,294

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Less valuation allowance	(110,305)	(103,431)
Total deferred tax assets	489	863
<b>Deferred tax liabilities:</b>		
Acquired intangible assets.	(489)	(863)
Total deferred tax liabilities	(489)	(863)
Net deferred tax assets	\$	\$



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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 \$6.9 million, \$13.8 million and \$20.7 million during the years ended December 31, 2009, 2008 and 2007, respectively. The amount of the valuation allowance for deferred tax assets associated with excess tax deduction from stock based compensation arrangement that is allocated to contributed capital if the future tax benefits are subsequently recognized is \$0.4 million.

A provision has not been made at December 31, 2009, for U.S. or additional foreign withholding taxes on undistributed earnings of the foreign subsidiary because it is the present intention of management to reinvest the undistributed earnings indefinitely in foreign operations.

As of December 31, 2009, we had federal net operating loss carryforwards of approximately \$165.8 million, which will expire in the years 2016 through 2029 and federal research and development tax credits of approximately \$7.7 million, which expire in the years 2018 through 2029.

As of December 31, 2009, we had net operating loss carryforwards for California state income tax purposes of approximately \$122.8 million, which expire in the years 2012 through 2029, and California state research and development tax credits of approximately \$8.1 million which do not expire.

As of December 31, 2009, we had net operating loss carryforwards for foreign income tax purposes of approximately \$17.7 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. Any additional equity issuances could trigger a limitation on our ability to use 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. As of 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.

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

	Year Ended December 31, 2009				Year Ended December 31, 2008			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 19,344	\$ 15,884	\$ 2,901	\$ 2,189	\$ 6,314	\$ 9,978	\$ 8,857	\$ 11,945
Net income (loss) attributable to Dynavax	\$ 5,101	\$ 4,110	\$ (9,506)	\$ (30,270)	\$ (12,429)	\$ (6,079)	\$ (5,420)	\$ 3,099
Basic net income (loss) per share attributable to Dynavax common stockholders	\$ 0.13	\$ 0.10	\$ (0.24)	\$ (0.73)	\$ (0.31)	\$ (0.15)	\$ (0.14)	\$ 0.08
Weighted-average shares used in computing basic net income (loss) per share	39,889	39,923	40,153	41,420	39,785	39,806	39,831	39,854
Diluted net income (loss) per share attributable to Dynavax common stockholders	\$ 0.13	\$ 0.10	\$ (0.24)	\$ (0.73)	\$ (0.31)	\$ (0.15)	\$ (0.14)	\$ 0.08
Weighted-average shares used in computing diluted net income (loss) per share	39,889	40,064	40,153	41,420	39,785	39,806	39,831	39,854

**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.

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.

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**(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, 2009. 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.

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**Report of Independent Registered Public Accounting Firm**

To The Board of Directors and Stockholders

Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2009, 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, 2009 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Francisco, California

March 15, 2010

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

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

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**ITEM 9B. OTHER INFORMATION**

None.

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**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 2010 Annual Meeting of Stockholders (the Proxy Statement), which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2009.

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 ACCOUNTANT 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

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Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

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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
4.1 <sup>(3)</sup>	Registration Rights Agreement
4.2 <sup>(3)</sup>	Form of Warrant
4.3 <sup>(4)</sup>	Form of Specimen Common Stock Certificate
4.4 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.5 <sup>(2)</sup>	Form of Rights Certificate
4.6 <sup>(6)</sup>	Form of Restricted Stock Unit Award Agreement.
4.7	Form of Amended Warrant
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 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



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<b>Exhibit Number</b>	<b>Document</b>
10.47	Amended Purchase Option Agreement, dated November 9, 2009, between Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.48	Warrant Purchase Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.49	Amended Registration Rights Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.50	Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
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

- (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.

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- (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.

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.

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**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.**

**President and Chief Executive Officer**

**(Principal Executive Officer)**

Date: March 16, 2010

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

**Vice President, Finance**

**(Principal Accounting and Financial Officer)**

Date: March 16, 2010

Signature	Title	Date
/s/ DINO DINA, M.D. <b>Dino Dina, M.D.</b>	President and Chief Executive Officer  <i>(Principal Executive Officer)</i>	March 16, 2010
/s/ JENNIFER LEW <b>Jennifer Lew</b>	Vice President, Finance <i>(Principal Accounting and Financial Officer)</i>	March 16, 2010
/s/ ARNOLD ORONSKY, PH.D. <b>Arnold Oronsky, Ph.D.</b>	Chairman of the Board	March 16, 2010
/s/ NANCY L. BUC <b>Nancy L. Buc</b>	Director	March 16, 2010
/s/ DENNIS CARSON, M.D. <b>Dennis Carson, M.D.</b>	Director	March 16, 2010
/s/ FRANCIS R. CANO, PH.D. <b>Francis R. Cano, Ph.D.</b>	Director	March 16, 2010
/s/ DENISE M. GILBERT, PH.D. <b>Denise M. Gilbert, Ph.D.</b>	Director	March 16, 2010
/s/ MARK KESSEL	Director	March 16, 2010

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**Mark Kessel**

/s/ DAVID LAWRENCE, M.D.  
**David M. Lawrence, M.D.**

Director

March 16, 2010

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

Director

March 16, 2010

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

Director

March 16, 2010

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<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
4.1 <sup>(3)</sup>	Registration Rights Agreement
4.2 <sup>(3)</sup>	Form of Warrant
4.3 <sup>(4)</sup>	Form of Specimen Common Stock Certificate
4.4 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.5 <sup>(2)</sup>	Form of Rights Certificate
4.6 <sup>(6)</sup>	Form of Restricted Stock Unit Award Agreement.
4.7	Form of Amended Warrant
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 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	Amended Purchase Option Agreement, dated November 9, 2009, between Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.

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<b>Exhibit Number</b>	<b>Document</b>
10.48	Warrant Purchase Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.49	Amended Registration Rights Agreement, dated as of November 9, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.50	Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
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
(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-Q 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.
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