

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 06, 2009

[Table of Contents](#)

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of)

33-0728374
(IRS Employer)

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

incorporation or organization)

Identification No.)

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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

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

Title of Each Class:
Common Stock, \$.001 Par Value

Name of Each Exchange on Which Registered:
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 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 ☒

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, 2008 as reported on the Nasdaq Global Market, was approximately \$56,503,897. 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.

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

As of February 27, 2009, the registrant had outstanding 39,922,469 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2009 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

Table of Contents

INDEX

DYNAVAX TECHNOLOGIES CORPORATION

	Page No.
<u>PART I</u>	
Item 1. <u>BUSINESS</u>	3
Item 1A. <u>RISK FACTORS</u>	17
Item 1B. <u>UNRESOLVED STAFF COMMENTS</u>	27
Item 2. <u>PROPERTIES</u>	27
Item 3. <u>LEGAL PROCEEDINGS</u>	27
Item 4. <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	27
<u>PART II</u>	
Item 5. <u>MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	28
Item 6. <u>SELECTED FINANCIAL DATA</u>	30
Item 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	31
Item 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	45
Item 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	46
Item 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	74
Item 9A. <u>CONTROLS AND PROCEDURES</u>	74
Item 9B. <u>OTHER INFORMATION</u>	75
<u>PART III</u>	
Item 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	76
Item 11. <u>EXECUTIVE COMPENSATION</u>	76
Item 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	76
Item 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	76
Item 14. <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	76
<u>PART IV</u>	
Item 15. <u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	76
<u>SIGNATURES</u>	76

Table of Contents

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our business strategy, 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, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) product candidates. Based on our proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. We have partnerships with leading pharmaceutical companies such as GlaxoSmithKline (GSK), AstraZeneca AB (AstraZeneca), and Novartis Vaccines and Diagnostics, Inc. (Novartis) as well as funding from Symphony Dynamo, Inc. (SDI) and the National Institutes of Health (NIH).

Our diversified pipeline of product candidates includes:

HEPLISAV™, a Phase 3 hepatitis B vaccine

SD-101, a Phase 1b hepatitis C therapy developed under our SDI funding agreement

DV-601, a Phase 1b proprietary hepatitis B therapy

Our Universal Flu vaccine, a preclinical vaccine under a supply and option agreement with Novartis

AZD1419, a preclinical asthma therapy partnered with AstraZeneca

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

DV1079, a preclinical autoimmune and inflammatory disease therapy partnered with GSK

Our objective is to build a product-based business with a portfolio of products focused on serious unmet medical needs. Our diversified pipeline includes TLR agonists and inhibitors and targets infectious, respiratory, autoimmune, and inflammatory diseases. We discover novel TLR product candidates based on our proprietary

Table of Contents

technologies, including immunostimulatory sequences (ISS) and immunoregulatory sequences (IRS), which are short DNA sequences. ISS enhance the ability of the immune system to fight disease and control chronic inflammation by specifically targeting TLRs found on a specialized subset of immune cells to alter the innate immune response. IRS specifically inhibit TLRs associated with autoimmune and inflammatory diseases.

Our strategies are focused on discovering novel compounds based on our proprietary technologies and developing our diversified pipeline of product candidates through partnerships with leading pharmaceutical companies or funding agreements. For our partnered products, we seek to leverage the experience and resources of our pharmaceutical partners to further the development and potentially commercialize these product candidates. For our other proprietary product candidates, we are developing these to evaluate the clinical potential with a goal of commercializing these products ourselves or through pharmaceutical partnerships.

The Immune System

The immune system is the body's natural defense mechanism against disease-causing agents, such as bacteria, viruses and parasites, and plays an important role in identifying and eliminating abnormal cells, such as cancer cells. The body's first line of defense is an immediate, rapid response called innate immunity that protects the body during the days or weeks needed for a second, longer-term immune response termed adaptive immunity to develop.

The diagram above is a visual representation of how the immune system reacts when it encounters antigen, or a foreign substance. The immune system's response to any foreign substance involves a cascade of events orchestrated by specialized immune cells, leading to either a Th1 or a Th2 response, as illustrated in the above diagram. Dendritic cells, a type of immune cell, have two key functions in the initial, innate immune response. First, they produce cytokines that help to kill viruses and bacteria. Second, they ensure that pathogens and other foreign substances are highly visible to specialized helper T cells, called Th1 and Th2 cells, which coordinate the longer-term adaptive immune response. Dendritic cells recognize different types of offending substances and are able to guide the immune system to make the most appropriate response. When viruses, bacteria and abnormal cells are encountered, dendritic cells trigger a Th1 response, whereas when a parasite infection is detected, dendritic cells initiate a Th2 response. Th1 and Th2 responses last for an extended time in the form of Th1 and Th2 memory cells, conferring long-term immunity.

The Th1 Response

The Th1 response involves the production of the body's most potent anti-infective weapons—specific cytokines, including interferon-alpha, interferon-gamma and interleukin 12 (IL-12), as well as killer T cells, a specialized immune cell. In addition, protective IgG antibodies are generated that also help rid the body of foreign antigens and allergens. Once a population of Th1 cells specific to a particular antigen or allergen is produced, it persists for a long time in the form of memory Th1 cells, enabling a more rapid and powerful

Table of Contents

immune response the next time exposure to that particular antigen or allergen occurs. An insufficient Th1 response to an infection can result in chronic disease, whereas an inappropriate Th1 response can cause diseases such as rheumatoid arthritis.

The Th2 Response

Activation of the Th2 response involves the production of other cytokines, IL-4, IL-5 and IL-13, which attract inflammatory cells such as eosinophils, basophils and mast cells, to destroy the invading organism. The Th2 response also leads to the generation of a specialized antibody, IgE, which can recognize antigens and allergens, and further enhance the protective response. An inappropriate Th2 immune response to allergens, such as plant pollens, can lead to chronic inflammation and result in allergic rhinitis, asthma and other allergic diseases. Subsequent exposures to the same allergens can reactivate memory Th2 cells, sustaining inflammation and leading to chronic disease.

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.

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 most of our preclinical programs, we use our advanced proprietary technologies that modify 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

Table of Contents

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.

Primary Development Programs

Our primary development programs are as follows:

Product Candidate	Clinical Indication(s)	Phase	Partnership/Funding Support
<i>Infectious Diseases</i>			
HEPLISAV	Hepatitis B prevention	Phase 3	Dynavax
SD-101	Hepatitis C infection	Phase 1b	Symphony Dynamo Inc.
DV-601	Hepatitis B infection	Phase 1b	Dynavax
<i>Respiratory Diseases</i>			
Universal Flu vaccine	Influenza prevention	Preclinical	Novartis (Supply and Option Agreement); NIH
AZD1419	Asthma	Preclinical	AstraZeneca AB
<i>Autoimmune and Inflammatory Diseases</i>			
DV1079	Autoimmune and inflammatory diseases	Preclinical	GlaxoSmithKline; NIH
HEPLISAV Hepatitis B Vaccine			

Our lead product candidate is HEPLISAV, a Phase 3 hepatitis B vaccine that has shown clinical benefits in our trials. Our 9 clinical trials conducted over the past 10 years have included approximately 2,500 individuals vaccinated with HEPLISAV. In August 2008, HEPLISAV met its primary endpoint in the largest clinical trial conducted to date, a Phase 3 trial known as PHAST (Phase 3 HeplisAv Short-regimen Trial).

HEPLISAV is based on our proprietary ISS that specifically target TLR9 to stimulate an innate immune response. This vaccine combines our first generation 1018 ISS with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax Europe facility in Düsseldorf, Germany. HEPLISAV is aimed at unmet needs in the vaccination of adults and end-stage renal disease (ESRD) patients by providing an increased response with fewer doses in a shorter period of time.

Clinical development was suspended in March 2008, when the U.S. Food and Drug Administration (FDA) placed a clinical hold on the two HEPLISAV Investigational New Drug (IND) Applications, one for healthy adults and one for ESRD patients. The FDA requested a review of the clinical and preclinical safety data related to HEPLISAV, including all available information about a single case of Wegener's granulomatosis, an uncommon form of vasculitis. In October 2008 and February 2009, the FDA requested additional information which the agency indicated may be helpful in its risk assessment of the two INDs and may assist in finding a development path forward for HEPLISAV for healthy adults and ESRD patients. At present, the two INDs remain on clinical hold in the United States. HEPLISAV has not been put on clinical hold by any regulatory authority outside the United States.

Table of Contents

We are seeking clarification of the remaining regulatory requirements for the development and licensure of HEPLISAV in the United States and Europe. There can be no assurance as to whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies or patient data. If the regulatory feedback favors continued development, we plan to pursue a partnership or financing arrangement to complete HEPLISAV's development. Dynavax holds all development, manufacturing, and commercialization rights to HEPLISAV following Merck & Co., Inc.'s termination of our collaboration agreement in December 2008.

Clinical Results

In the largest clinical trial conducted to date, known as PHAST, 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®¹ administered at 0, 1, and 6 months. The primary endpoint was the proportion of subjects who developed protective antibody to hepatitis B after receiving a full course of vaccination.

Immunogenicity results from this trial demonstrated that subjects receiving HEPLISAV were seroprotected with fewer doses and at an earlier time point than subjects receiving Engerix-B. Results showed 95.1 percent 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 percent of subjects who received three doses of Engerix-B at 0, 1, and 6 months when measured at 28 weeks.

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.

Commercial Opportunity

We estimate the hepatitis B vaccine market for healthy adults and ESRD patients worldwide to be approximately \$500 million annually. There can be no assurance that HEPLISAV will be approved for these market segments in any particular territory.

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 usually require 3 doses given over 6 months to provide seroprotection of approximately 30%, 75%, and 90% after the first, second, and third doses respectively. Vaccines provide seroprotection to only approximately 75% of persons over 60 years of age after 3 doses and also fail to provide seroprotection to a large percentage of immunocompromised persons, such as ESRD patients. The effectiveness of current vaccines is further compromised because only 30% of people receive all 3 doses.

HEPLISAV is designed to address the limitations of current vaccines by delivering complete vaccination in fewer doses and 5 months earlier than current vaccines. In addition, previous clinical data have demonstrated that HEPLISAV can provide an increased response for older and immunocompromised individuals. Greater prevention of disease could be attained with use of HEPLISAV where individuals could be seroprotected with fewer doses and at an earlier time point than with current vaccines.

¹ Engerix-B® is a registered trademark of GlaxoSmithKline.

Table of Contents

SD-101 Hepatitis C Therapy

SD-101 is our hepatitis C therapy and is being evaluated in an ongoing Phase 1b clinical trial. This therapy utilizes a novel Type C TLR9 agonist based on our second-generation ISS and may offer a more effective therapeutic option for patients chronically infected with the hepatitis C virus (HCV). We are developing SD-101 through our Symphony Dynamo, Inc. funding agreement. SD-101 is designed to be a potential replacement for interferon alpha therapy and be used in combination with oral antiviral therapy to stop HCV viral replication and induce a long-lasting immune response.

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP and certain of its affiliates (Symphony) to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development (Development Programs). The agreements provided for the formation of Symphony Dynamo, Inc. (SDI). Pursuant to the agreements, Symphony invested \$50 million in SDI to fund the Development Programs, and we licensed to SDI our intellectual property rights related to the Development Programs. The current status of SDI is discussed below under *Symphony Dynamo Inc.*

Commercial Opportunity

According to the World Health Organization, there are over 170 million people worldwide chronically infected with HCV. Analysts estimate the worldwide market for HCV therapies will grow from approximately \$3 billion in 2008 to over \$10 billion by 2015. There is no vaccine available to prevent HCV, a disease of the liver that can lead to cirrhosis of the liver and hepatocellular carcinoma.

Current therapy consists of pegylated interferon alpha and the antiviral drug ribavirin and is effective in treating only half of all patients infected with HCV. This standard of care is significantly less effective in genotype 1 carriers, which represent 70% of all HCV carriers in the United States and Europe. In addition, treatment with these therapies can cause significant side effects, including severe depression and anemia.

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 oral antiviral therapy, may stop HCV viral replication and induce a long-lasting immune response and could become a potential replacement for interferon alpha therapy, although there can be no assurance that SDI-101 can achieve such outcome or address the current market for interferon alpha therapy.

DV-601 Hepatitis B Therapy

DV-601 is our proprietary hepatitis B therapy and is in Phase 1 clinical trial development. This novel treatment approach for the first time combines both the surface and core hepatitis B virus (HBV) antigens. 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.

Commercial Opportunity

Over 350 million individuals worldwide are chronically infected with HBV, which can lead to cirrhosis of the liver and hepatocellular carcinoma. Analysts estimate the current worldwide market for HBV therapies to be approximately \$1 billion annually. Current treatment aims to halt progression of the disease and consist of either indefinite use of antiviral medication 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.

Table of Contents

Our HBV therapy, being studied in combination with an antiviral, is expected to induce a potent immune response against HBV-infected cells and offer a more effective and shorter duration therapeutic option for chronically infected patients.

Preclinical Programs

In addition to our clinical-stage product candidates, our pipeline includes preclinical programs for influenza, asthma and chronic obstructive pulmonary disease (COPD), and autoimmune and inflammatory diseases.

Universal Flu Vaccine

Our Universal Flu vaccine candidate is being developed to address unmet needs in controlling influenza by providing broad immunity to divergent flu strains and enhanced efficacy against strains in the trivalent seasonal vaccine. Our vaccine candidate will include:

M2e/NP-ISS: A proprietary fusion protein comprised of two conserved influenza antigens, the extracellular domain of the matrix 2 protein (M2e) and nucleoprotein (NP), linked to our second-generation ISS

Trivalent influenza vaccine (TIV)

The M2e/NP-ISS fusion protein conjugate may offer the benefits of cross-strain protection, dose sparing, and enhanced immunogenicity. M2e/NP-ISS is expected to enable subjects to generate M2e-specific cytotoxic protective antibodies and NP-specific cytotoxic T-cell protection, as well as enhance the strain-specific neutralizing antibodies induced by the trivalent influenza vaccine.

Novartis is supplying the trivalent influenza vaccine component for clinical and commercial use and has an exclusive option to negotiate a joint development and commercialization agreement. Our research and development program for our Universal Flu vaccine has been partially funded by grants from the NIH.

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.

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

Our Universal Flu vaccine candidate is being developed to address many of the challenges of current vaccines with the goal of providing broad immunity against divergent influenza strains, increasing the efficacy of seasonal vaccines, and potentially providing dose-sparing and increasing the quantity of vaccine available.

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

Table of Contents

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. We are currently working on a second candidate drug and have extended our research collaboration with AstraZeneca to provide research funding for a third candidate.

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.

DV1079 (IRS) for Autoimmune and Inflammatory Diseases

We have pioneered a new approach to treating autoimmune and inflammatory diseases with our first-in-class TLR inhibitors called IRS. Our lead inhibitor product candidate is DV1079, a bifunctional inhibitor of TLR7 and TLR9. We are developing our TLR inhibitor programs under our worldwide strategic alliance with GSK established in December 2008.

In animal studies as well as in-vitro, our TLR inhibitors have demonstrated broad potential in multiple autoimmune disease models, such as lupus, inflammatory skin disorders, and rheumatoid arthritis. Our inhibitors have a highly-targeted effect on key immune cells and pathways that play a role in autoimmune and inflammatory diseases. Specifically, our TLR inhibitors target two types of immune cells, B cells and PDC, which 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.

Commercial Opportunity

Over 20 million individuals in the U.S. and Europe have autoimmune diseases such as lupus, psoriasis, and rheumatoid arthritis. Analysts estimate that key biologic drugs used to treat these conditions generate over \$20 billion in worldwide sales each year. Currently marketed therapies are broadly immunosuppressive with variable efficacy and substantial toxicity. Our TLR inhibitors have demonstrated a highly targeted effect on key immune cells and pathways that play a role in multiple autoimmune and inflammatory diseases.

Pharmaceutical Partnerships and Funding Agreements

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

Table of Contents

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 tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one specified product under the collaboration.

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 based on product sales. 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. We are currently working on a second candidate drug, and in February 2009, we extended our research collaboration with AstraZeneca to provide funding for a third candidate drug.

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 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. Should the option not be exercised, 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.

Symphony Dynamo, Inc.

In April 2006, we entered into a \$50 million funding agreement with Symphony Capital Partners, LP and its co-investors. Under this agreement, Symphony Dynamo, Inc. (SDI) was formed to develop novel TLR9 agonist products for hepatitis C, hepatitis B and cancer. Although SDI holds the intellectual property rights to these products, we have an option which allows us the exclusive right, but not the obligation, to acquire certain or all of the programs at specified points of time during the five year agreement. In April 2007, we exercised our option to acquire the rights to our hepatitis B therapy program and triggered a payment obligation of \$15 million which is due upon the expiration of the SDI Collaboration in 2011, if the purchase option for all programs is not exercised. In December 2008, we discontinued the cancer program to focus on the hepatitis C therapy program. We have retained the right to seek strategic partners for the future development and commercialization of the cancer and hepatitis C therapy products.

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 retained 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

Table of Contents

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.

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.

Our intellectual property portfolio includes issued patents and patent applications claiming compositions and formulations of ISS and IRS, their methods of use and processes for their manufacture. Some of these patents and applications are exclusively licensed to us under agreements with the Regents of the University of California.

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 and pay royalties on net sales resulting from successful products originating from the licensed technologies. 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.

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.

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.

Table of Contents

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.

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 and Crucell N.V., among others. There are

Table of Contents

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 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 Schering-Plough Corporation. Other companies, such as Vertex Pharmaceuticals, Inc./Tibotec Pharmaceuticals, Schering-Plough, 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, Schering-Plough, Gilead Sciences, Inc., 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 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 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., Novartis, AstraZeneca, Schering-Plough and GSK. In addition, directly competing products are in development by Idera Pharmaceuticals/Novartis and Sanofi-aventis/Pfizer Inc.

Our therapy for autoimmune and inflammatory diseases, DV-1079, 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 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

Table of Contents

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 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.

Table of Contents

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, 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 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.

Table of Contents

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.

Employees

As of December 31, 2008, we had 155 full-time employees, including 28 Ph.D.s, 2 M.D.s and 15 others with advanced degrees. Of the 155 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. 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.

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 \$248.7 million as of December 31, 2008. 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. Our current grants are scheduled to terminate in 2010, although we recently received a five-year government contract totaling \$17 million. 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. The clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect and our partner for this product has notified us of termination of our collaboration agreement. Clinical trials for certain of our other product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

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

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

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

Table of Contents

If we are unable to secure additional funding, we will have to reduce or discontinue operations.

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding in the current financing environment may not allow us to continue operations as currently planned. We may be unable to obtain additional capital on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations.

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

None of our product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced product candidates. The clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect. Approval processes in the United States 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. For example, in October 2008 the FDA communicated that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children, but advised us that there may be an acceptable risk versus potential benefit profile for ESRD patients. In February 2009, the FDA requested additional clinical and safety information which the agency indicated may be helpful in its risk assessment of the two INDs and may assist in finding a development path forward for HEPLISAV, not only in ESRD patients but also in healthy adults. There can be no assurance as to whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies or patient data. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations.

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

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

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA. Any extension, suspension, 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;

Table of Contents

potentially diminish any competitive advantages for those products;

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

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

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

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

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

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

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

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

Our most advanced product candidate in clinical trials is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay or discontinue all of our clinical trials. For example, since March 2008, HEPLISAV has been and remains on clinical hold following a SAE that occurred in the PHAST clinical trial. As most of our clinical product candidates contain ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

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

Table of Contents

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

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

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The clinical hold on the two U.S. IND Applications for HEPLISAV has remained in effect since March 2008. There can be no assurance as to whether HEPLISAV can be further developed. Moreover, if HEPLISAV can not be successfully developed, we will have to re-purpose our Düsseldorf facility toward 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 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 or terminated. Any extension, delay or termination of our clinical trials would delay 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 successfully commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community. 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. 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. We also intend to enter into collaborative relationships to provide funding to support our research and development programs. The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators 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. 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

Table of Contents

us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

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

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to treat or prevent infectious diseases, allergy, asthma and cancer, as well as those focusing more generally on the immune system. 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.

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

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

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

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

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

compliance with varying international regulatory requirements, laws and treaties;

securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

Table of Contents

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.

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 our licenses from the Regents of the University of California. 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 with the Regents of the University of California, or UC. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate our agreements or convert exclusive to non-exclusive licenses. In addition, our license agreements with UC 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.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of 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 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.

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 United States, 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 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, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, 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 the U.S. other than with respect to HEPLISAV. Such a license may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

Table of Contents

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 United States and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the United States, legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

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

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

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

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

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

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

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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

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

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

We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some

Table of Contents

or all of the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise our option prior to the expiration of the development period, and even if we decide to exercise, we may not have the financial resources to exercise our option in a timely manner.

In April 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapies (Development Programs) to Symphony Dynamo, Inc. (SDI) in consideration for a commitment from Symphony Capital Partners, LP and certain of its affiliates (Symphony) to provide \$50 million of capital to advance the Development Programs. As part of the arrangement, we received an exclusive purchase option (Purchase Option) to acquire all of the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices ranging from \$89.4 million as of January 1, 2009, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The intellectual property rights to the remaining cancer and hepatitis C therapy programs not purchased through the exercise of the Purchase Option will remain with SDI.

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

If we elect to exercise the Purchase Option, we will be required to make a payment of at least \$89.4 million, increasing thereafter quarterly, which at our discretion may be paid partially in shares of our common stock. As a result, in order to exercise the Purchase Option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the Purchase Option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the Purchase Option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.

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

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

Table of Contents

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors. 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. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

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

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

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

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

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

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 enter into and maintain collaborations;

maintenance of our existing exclusive licensing agreements with the Regents of the University of California;

Table of Contents

changes in government regulations, general economic conditions, 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. In November 2008, we transferred our listing of Dynavax shares to The Nasdaq Capital Market from The Nasdaq Global Market. We may be delisted from the Nasdaq Capital Market if our share price or market value of publicly held shares does not meet certain thresholds. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

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

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

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

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

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

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

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

Our recently adopted 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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of the Common Shares or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

Table of Contents

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

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

ITEM 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

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

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
2008		
First Quarter	\$ 6.55	\$ 1.87
Second Quarter	\$ 2.59	\$ 1.40
Third Quarter	\$ 2.04	\$ 0.97
Fourth Quarter	\$ 2.60	\$ 0.15
2007		
First Quarter	\$ 9.24	\$ 4.56
Second Quarter	\$ 5.81	\$ 3.98
Third Quarter	\$ 5.19	\$ 3.60
Fourth Quarter	\$ 5.80	\$ 4.17

As of February 27, 2009, there were approximately 104 holders of record of our common stock, as shown on the records of our transfer agent. The number of record holders does not include shares held in "street name" through brokers.

Dividends

We do not pay 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.

Use of Proceeds from Sales of Registered Securities

On December 27, 2007, pursuant to agreements with Deerfield, we issued to Deerfield Management and their affiliates warrants to purchase 1,000,000 shares of our common stock at a price of \$5.65 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.71 per share. 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 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates. In August 2008, the Company and Deerfield entered into a Settlement and Mutual Release agreement to amend this warrant to provide a termination date of February 26, 2014. In addition, 700,000 of the 1,000,000 shares issued on December 27, 2007, have been amended to allow for a reduction in exercise price equal to the average daily volume weighted average price over the 15 trading days prior to August 26, 2009, if such weighted average price is below \$4.00 per share.

On October 18, 2007, pursuant to agreements with Deerfield, we issued to Deerfield Management and their affiliates warrants to purchase 1,300,000 shares of our common stock at a price of \$5.75 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.79 per share. We filed a registration statement on Form S-3 (File No. 333-147455) on November 16, 2007, as amended on November 30, 2007 with

Table of Contents

the Securities and Exchange Commission and the related prospectus supplement dated December 5, 2007 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates. In August 2008, the Company and Deerfield entered into a Settlement and Mutual Release agreement to amend this warrant to provide a termination date of February 26, 2014 and a reduction in exercise price to \$1.68 per share.

On July 18, 2007, pursuant to agreements with Deerfield, we issued to Deerfield Management and their affiliates warrants to purchase 1,250,000 shares of our common stock at a price of \$5.13 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.36 per share. 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 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates. In August 2008, the Company and Deerfield entered into a Settlement and Mutual Release agreement to amend this warrant to provide a termination date of February 26, 2014.

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 April 18, 2006, pursuant to agreements with Symphony Capital Partners, LP, we issued to Symphony Dynamo Holdings LLC a five-year warrant to purchase 2,000,000 shares of our common stock at a price of \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. We filed a registration statement on Form S-3 (File No. 333-134688) on June 1, 2006 covering the resale of share of common stock subject to purchase pursuant to the warrants, and the warrants were issued pursuant to Rule 506 promulgated under Regulation D.

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, 2008, 2007 and 2006 and the Consolidated Balance Sheets Data as of December 31, 2008 and 2007 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, 2005 and 2004 and the Consolidated Balance Sheets Data as of December 31, 2006, 2005 and 2004 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.

	2008(1)	Years Ended December 31, 2007(1) 2006(1) 2005 2004 (In thousands, except per share data)			
Consolidated Statements of Operations Data:					
Total revenues	\$ 37,094	\$ 14,093	\$ 4,847	\$ 14,655	\$ 14,812
Operating expenses:					
Research and development(2)	44,771	65,888	50,116	27,887	23,129
General and administrative	15,463	18,293	14,836	9,258	8,543
Acquired in-process research and development(3)			4,180		
Amortization of intangible assets	980	1,004	698		
Total operating expenses	61,214	85,185	69,830	37,145	31,672
Loss from operations	(24,120)	(71,092)	(64,983)	(22,490)	(16,860)
Interest and other income, net	1,741	4,165	3,287	2,125	919
Debt forgiveness	5,000				
Interest expense	(9,157)	(1,719)	(99)	(190)	(30)
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(26,536)	(68,646)	(61,795)	(20,555)	(15,971)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	5,707	8,675	9,743		
Net loss	\$ (20,829)	\$ (59,971)	\$ (52,052)	\$ (20,555)	\$ (15,971)
Basic and diluted net loss per share	\$ (0.52)	\$ (1.51)	\$ (1.61)	\$ (0.79)	\$ (0.75)
Shares used in computing basic and diluted net loss per share	39,819	39,746	32,339	25,914	21,187

- (1) Our net loss for the years ended December 31, 2008, 2007, and 2006 includes approximately \$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 Statement of Financial Accounting Standards No. 123R, Share-Based 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. For a description of these charges, see Note 6 to the Consolidated Financial Statements.
- (3) Represents acquired in-process research and development. The amount for 2006 relates to the Rhein Biotech GmbH acquisition. For description of these charges, see Note 6 to the Consolidated Financial Statements.

Table of Contents

	2008	2007	December 31, 2006 (In thousands)	2005	2004
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	\$ 43,367	\$ 56,617	\$ 72,831	\$ 75,110	\$ 65,844
Investments held by Symphony Dynamo, Inc.	25,109	31,631	13,363		
Working capital	35,688	82,035	75,985	71,941	64,017
Total assets	90,623	120,449	102,890	80,093	73,646
Noncontrolling interest in Symphony Dynamo, Inc.	2,634	8,341	2,016		
Accumulated deficit	(248,743)	(227,914)	(167,943)	(115,891)	(95,336)
Total stockholders' equity	13,522	30,790	77,056	74,363	59,876

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 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, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) product candidates. Based on our proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. We have partnerships with leading pharmaceutical companies such as GlaxoSmithKline (GSK), AstraZeneca AB (AstraZeneca), and Novartis Vaccines and Diagnostics, Inc. (Novartis) as well as funding from Symphony Dynamo, Inc. (SDI) and the National Institutes of Health (NIH).

Our diversified pipeline of product candidates includes:

HEPLISAV™, a Phase 3 hepatitis B vaccine

SD-101, a Phase 1b hepatitis C therapy developed under our SDI funding agreement

DV-601, a Phase 1b proprietary hepatitis B therapy

Our Universal Flu vaccine, a preclinical vaccine under a supply and option agreement with Novartis

AZD1419, a preclinical asthma therapy partnered with AstraZeneca

DV1079, a preclinical autoimmune and inflammatory disease therapy partnered with GSK

Our objective is to build a product-based business with a portfolio of products focused on serious unmet medical needs. Our diversified pipeline includes TLR agonists and inhibitors and targets infectious, respiratory, autoimmune, and inflammatory diseases. We discover novel TLR product candidates based on our proprietary technologies, including immunostimulatory sequences (ISS) and immunoregulatory sequences (IRS), which are

Table of Contents

short DNA sequences. ISS enhance the ability of the immune system to fight disease and control chronic inflammation by specifically targeting TLRs found on a specialized subset of immune cells to alter the innate immune response. IRS specifically inhibit TLRs associated with autoimmune and inflammatory diseases.

Our strategies are focused on discovering novel compounds based on our proprietary technologies and developing our diversified pipeline of product candidates through partnerships with leading pharmaceutical companies or funding agreements. For our partnered products, we seek to leverage the experience and resources of our pharmaceutical partners to further the development and potentially commercialize these product candidates. For our other proprietary product candidates, we are developing these to evaluate the clinical potential with a goal of commercializing these products ourselves or through pharmaceutical partnerships.

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. In accordance with SAB 104, 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 collectibility is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under the provisions of EITF 00-21. 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 the provisions of EITF 00-21, 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.

Table of Contents

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

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

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

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards. 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. Agreements entered into after January 1, 2008 are evaluated under the provisions of EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* which requires the Company to defer and capitalize costs related to non-refundable advance payments for good or services to be received in the future for use in research and development activity. The capitalized amounts are 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

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, *Share-Based Payment*, or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

Table of Contents

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards. We have elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects, if any, of stock-based compensation expense pursuant to FAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of FAS 123R.

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. 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.

Acquired In-process Research and Development

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To determine the value of the acquired in-process research and development associated with the Rhein Biotech GmbH transaction, we used the income approach and the cost approach. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for distribution to the investors in the asset. We performed a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process research and development is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur.

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 purchase 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 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 as required by SFAS No. 142, Goodwill and Other Intangible Assets.

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 in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of

Table of Contents

Long-Lived Assets 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

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

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

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

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

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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

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

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

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

The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC (Holdings) and its wholly-owned subsidiary SDI. Pursuant to the Funding Agreement, Symphony invested \$50.0 million in Holdings (\$20.0 million at closing and an additional \$30.0 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Table of Contents

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock, which Holdings distributed to Symphony, at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share if either of two events occurs: (a) we enter into a collaboration agreement with a third party for a specified oncology program; or (b) the Purchase Option is terminated or expires unexercised. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model and was recorded in additional paid in capital.

SDI is governed by a separate board of directors, which is comprised of 5 members. Our CEO serves as a board member and we have the right to approve the two independent directors serving on the board. Additionally, our Chief Scientific Officer serves as the chairman of the SDI joint development committee, which is responsible for overseeing and monitoring the Development Programs for which we have been contracted to perform services.

Under FASB Interpretation No. 46 (FIN 46R), Consolidation of Variable Interest Entities, a variable interest entity (VIE) is (1) an entity that has equity that is insufficient to permit the entity to finance its activities without additional subordinated financial support, or (2) 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. FIN 46R requires a VIE 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. The application of FIN 46R to a given arrangement requires significant management judgment.

We have consolidated the financial position and results of operations of SDI in accordance with FIN 46R. 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.

FIN 46R deems parties 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 will continue to oversee and monitor the Development Programs, (3) our employees will continue 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 have the ability to participate in the benefits of a successful development effort.

Symphony will be required to absorb the development risk for its equity investment in SDI. Pursuant to FIN 46R's requirements, Symphony's equity investment in SDI is 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 perform the research and development on behalf of SDI, our development risk is 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 will be paid to Symphony at the expiration of the SDI collaboration in 2011 if we do not exercise the Purchase Option, or will be included as part of the applicable purchase price upon exercise of the Purchase Option.

Table of Contents

Net losses incurred by SDI are charged to the noncontrolling interest until that balance has been reduced to zero, at which point our net loss will be increased for the losses incurred by SDI subsequent to that date. At December 31, 2008, the noncontrolling interest balance was \$2.6 million, which we currently expect to be exhausted in 2010. As of December 31, 2008, the investments held by SDI were \$25.1 million, which we expect will be spent on the Development Programs through the term of the collaboration in 2011.

If we do not exercise the Purchase Option, we would remain obligated to pay Symphony \$15.0 million for the Program Option, which we have reflected as a liability at December 31, 2008. Furthermore, if the Purchase Option expires unexercised, we would then be required to deconsolidate SDI. That potential deconsolidation would not be expected to impact our earnings because the carrying value of the net assets of SDI would be expected to be zero.

In contrast, if we exercise the Purchase Option, we will gain control of SDI. As such, we would expect to record the exercise of the Purchase Option as a return to the noncontrolling interest. We do not expect to recognize an asset for the Purchase Option payment to be made to Symphony. Instead, the payment is expected to be accounted for as a capital transaction that would not affect our net income or loss. However, because the exercise of the Purchase Option will be accounted for as a capital transaction, it will be treated as a deemed dividend for purposes of reporting earnings per share, increasing loss per share or decreasing income per share, as the case may be, in the period we exercise the Purchase Option. If the Development Programs are successful and the resources are available, we currently expect to exercise the Purchase Option.

Results of Operations**Revenues**

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

The following is a summary of our revenues for the years ended December 31, 2008, 2007 and 2006 (in thousands, except for percentages):

Revenues:	Years Ended December 31,			Increase (Decrease) from		Increase (Decrease) from	
	2008	2007	2006	2007 to 2008		2006 to 2007	
	\$	\$	\$	\$	%	\$	%
Collaboration revenue	\$ 31,666	\$ 9,315	\$ 1,557	\$ 22,351	240%	\$ 7,758	498%
Grant revenue	2,999	3,046	1,549	(47)	(2)%	1,497	97%
Services and license revenue	2,429	1,732	1,741	697	40%	(9)	(1)%
Total revenues	\$ 37,094	\$ 14,093	\$ 4,847	\$ 23,001	163%	\$ 9,246	191%

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.

Table of Contents

Total revenues for the year ended December 31, 2007 increased by \$9.2 million, or 191%, over the same period in 2006 primarily due to an increase in revenue recognized from our collaboration agreements with Merck and AstraZeneca, which we entered into in October 2007 and September 2006, respectively. Grant revenue for the year ended December 31, 2007 included an increase of \$0.6 million associated with our NIH awards, following the resolution of a vendor restriction. In addition, the Company recognized approximately \$0.5 million in revenue for the year ended December 31, 2007 related to the August 2007 grant from the NIH for development of our Universal Flu vaccine. Services and license revenue of \$1.7 million was derived primarily from R&D services provided to customers of Dynavax Europe.

We anticipate that our revenues will increase in 2009 as compared to 2008. As a result of Merck's termination of the collaboration, we expect to recognize approximately \$28.5 million of remaining deferred revenue associated with the upfront payment from Merck on a ratable basis through the effective date of the termination, which is June 2009. In addition, Merck is obligated to make certain mutually agreed-upon payments to us for the 180-day wind down period through June 2009.

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):

	Years Ended December 31,			Increase (Decrease) from 2007 to 2008		Increase (Decrease) from 2006 to 2007	
	2008	2007	2006	\$	%	\$	%
Research and Development:							
Compensation and related personnel costs	\$ 18,020	\$ 19,170	\$ 13,006	\$ (1,150)	(6)%	\$ 6,164	47%
Outside services	18,477	38,726	31,042	(20,249)	(52)%	7,684	25%
Facility costs	6,872	6,414	4,988	458	7%	1,426	29%
Impairment		444		(444)	(100)%	444	100%
Non-cash stock-based compensation	1,402	1,134	1,080	268	24%	54	5%
Total research and development	\$ 44,771	\$ 65,888	\$ 50,116	\$ (21,117)	(32)%	\$ 15,772	31%

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. We discontinued clinical development of TOLAMBA, our ragweed allergy product candidate, in May 2008.

Research and development expenses for the year ended December 31, 2007 increased by \$15.8 million, or 31%, over the same period in 2006. The increase from fiscal 2006 was primarily due to outside services. In addition to the non-recurring \$5 million license payment, the remaining growth in outside services was due to increased clinical trial costs related to our product candidates HEPLISAV and TOLAMBA and expenses incurred to support SDI programs and Dynavax Europe operations. Compensation and related personnel costs increased in 2007 due to continued organizational growth to further develop our clinical candidates and the impact of a full year of operations from Dynavax Europe. Facility costs increased primarily due to rent expense for Dynavax Europe and higher operating costs in the U.S.

Table of Contents

Research and development expenses for 2007 also included approximately \$0.4 million of impairment charges related to the Supervax program. In 2006, we acquired the Supervax hepatitis B vaccine manufactured by Dynavax Europe. Supervax was launched in Argentina in December 2006 and was approved for marketing and sales through a third party distributor. We recorded immaterial revenues and expenses related to the manufacture and sale of formulated bulk vaccine in 2006 to the third party distributor. During the fourth quarter of 2007, we were notified that the distributor was unable to meet its annual commitment to order additional bulk vaccine due to its inability to sell all of the previously purchased Supervax product in the Argentine market. The underperformance of the Supervax program relative to originally expected future sales caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. As a result, we determined that estimated future cash flows from sales of Supervax were significantly less than the projection established at the time of acquisition, and we considered this an indicator of impairment. As of November 2007, we performed our impairment test of long-lived assets. Based on our analysis, the fair value of the acquired intangible asset (developed technology) and inventory associated with the Supervax program was estimated to be zero; therefore, we recorded a permanent write down of these assets in accordance with SFAS No. 144.

We anticipate that our research and development expenses in 2009 will remain consistent with 2008 expenses, if HEPLISAV development continues.

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 2007 to 2008		Increase (Decrease) from 2006 to 2007	
	2008	2007	2006	\$	%	\$	%
General and Administrative:							
Compensation and related personnel costs	\$ 6,810	\$ 7,101	\$ 6,264	\$ (291)	(4)%	\$ 837	13%
Outside services	4,209	5,248	4,008	(1,039)	(20)%	1,240	31%
Legal costs	1,696	2,951	1,727	(1,255)	(43)%	1,224	71%
Facility costs	973	610	591	363	60%	19	3%
Other			43			(43)	(100)%
Non-cash stock-based compensation	1,775	2,383	2,203	(608)	(26)%	180	8%
Total general and administrative	\$ 15,463	\$ 18,293	\$ 14,836	\$ (2,830)	(15)%	\$ 3,457	23%

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.

General and administrative expenses for the year ended December 31, 2007 increased by \$3.5 million, or 23%, compared to the same period in 2006. The increase primarily reflects additional legal costs associated with patent activities. Compensation and related personnel costs increased in 2007 as a result of overall organizational growth including the operations of Dynavax Europe. Outside services increased in 2007 related to higher professional fees incurred to support various corporate activities, SDI programs and Dynavax Europe operations.

We expect general and administrative expenses to decline in 2009 as compared to 2008, resulting from continued efforts to reduce outside service costs.

Table of Contents***Acquired In-process Research and Development***

Following our April 2006 acquisition of Rhein Biotech GmbH (Rhein), we recorded the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. As a result, we recorded net tangible assets of \$3.0 million, goodwill of \$2.3 million, other intangible assets of \$5.1 million, and expense associated with the acquired in-process research and development of \$4.2 million, representing the fair value of research projects that had not yet reached technological feasibility and that had no alternative future use.

A summary of the acquired in-process research and development programs and of the value assigned and recognized as expense as of the acquisition date is as follows (in thousands):

Program	Description	Estimated Acquisition Date Fair Value
Supervax	A hepatitis B vaccine launched in Argentina in December 2006 and approved for marketing and sales through a third party distributor	\$ 890
Theravax	A potential therapy for treatment of chronic Hepatitis B infection	2,740
Cytovax	A potential prophylactic vaccine to prevent infection from cytomegalovirus	550
		\$ 4,180

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Supervax program was determined using the income approach, which discounts expected future cash flows to present value. We estimated the related future net cash flows between 2006 and 2020 and discounted them to their present value using a risk-adjusted discount rate of 50%, which was based on the estimated internal rate of return for Rhein's operations and was comparable to the estimated weighted average cost of capital for companies with Rhein's profile. The projected cash flows from the Supervax program were based on key assumptions such as estimates of revenues and operating profits related to the program considering its stage of development; the time and resources needed to complete the development and approval of the related product; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Given the high risk associated with the development of new drugs, we adjusted the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process.

From the acquisition date through the year ended December 31, 2006, we continued registration activities for Supervax in territories other than Argentina. Actual sales for the fiscal year ended 2006 of Supervax in Argentina, while immaterial, were substantially in accordance with the original projections at the valuation date. During fiscal year 2007, we continued to monitor sales of Supervax in Argentina and we continued efforts to market Supervax in order to determine if we could achieve planned regulatory approvals in other markets. However, the lack of performance of the Supervax program under our distribution arrangement caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. For the year ended December 31, 2007, we recorded an impairment charge of \$0.4 million to write off the intangible asset and inventory associated with the Supervax program.

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Theravax and Cytovax programs was determined using the cost approach. We considered the stage of product development and the nature of these projects. At the valuation date, both Theravax and Cytovax were in early stages of development and were many years away from obtaining regulatory approval, if at all, and the risks associated with identifying material cash flows as well as the nature, timing and projected costs associated with the remaining efforts for completion of the projects were not reasonably estimable. However, we were able to estimate the cost involved in recreating the technology using historical data from Rhein, including cost and effort

Table of Contents

applied to the development of the technology prior to the acquisition date. We did not anticipate significant cash inflows for Theravax or Cytovax. Significant appraisal assumptions included historical data related to personnel effort, costs associated with those efforts, and external costs in order to estimate the fair value of these products as of the acquisition date.

In early 2007, we made a strategic decision to discontinue development of Cytovax in order to focus on other opportunities in our product pipeline; however, due to the early stage of development, there was no impact to our results of operations and financial condition. We intend to continue further development of our therapy to treat chronic hepatitis B infection, DV-601.

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, \$1.0 million and \$0.7 million for the years ended December 31, 2008, 2007 and 2006, 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 2007 to 2008		Increase (Decrease) from 2006 to 2007	
	2008	2007	2006	\$	%	\$	%
Interest and other income	\$ 1,741	\$ 4,165	\$ 3,287	\$ (2,424)	(58)%	\$ 878	27%
Loan forgiveness	\$ 5,000	\$	\$	\$ 5,000	100%	\$	
Interest expense	\$ (9,157)	\$ (1,719)	\$ (99)	\$ 7,438	433%	\$ 1,620	1,636%

Interest and other income for the year ended December 31, 2008 decreased by \$2.4 million, or 58%, compared to the same period in 2007 due primarily to lower investment balances and the decline in returns on our investment portfolio resulting from current market conditions. Interest and other income for the year ended December 31, 2007 increased by \$0.9 million, or 27%, over the same period in 2006. The increase reflects additional interest earned on the investments held by SDI and the investment of proceeds from upfront fees received in the fourth quarter of 2007.

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

Interest expense for the year ended December 31, 2008 increased by \$7.4 million, or 433%, compared to the same period in 2007 due to interest expense incurred from the termination of the loan agreement with Deerfield and amendments to warrants issued to Deerfield. Interest expense for the year ended December 31, 2007 increased by \$1.6 million, or 1,636%, over the same period in 2006 due to interest expense incurred from the commitment fees and warrants issued under the Deerfield financing agreement.

Amount Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.

Pursuant to the agreements that we entered into with SDI in April 2006 and, in accordance with FIN 46R, the results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006. In accordance with FIN 46R, we have deducted the losses attributed to the

Table of Contents

noncontrolling interest in the determination of net loss in our consolidated statements of operations, and we will continue to deduct such losses until the carrying amount of the noncontrolling interest in the consolidated balance sheet is reduced to zero. For the fiscal years ended December 31, 2008, 2007 and 2006, the loss attributed to the noncontrolling interest was \$5.7 million, \$8.7 million, and \$9.7 million, respectively.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact of the adoption of SFAS 160 on our consolidated results of operations and financial condition. SFAS 160 could change our accounting for the noncontrolling interest in SDI, a variable interest entity which we consolidate. Under current accounting standards, we do not reduce the carrying value of the noncontrolling interest below zero. Under SFAS 160, the noncontrolling interest could have a negative carrying value. In addition, upon adoption, we plan to reclassify the noncontrolling interest on our consolidated balance sheet from mezzanine to stockholders' equity.

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaboration Agreements*, which required certain income statement presentation of transactions with third parties and of payments between parties to the collaboration arrangement, along with disclosure about the nature of the arrangement. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated results of operations and financial condition.

In March 2007, the FASB discussed EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which addressed the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus was not permitted. Accordingly, we adopted EITF 07-3 in the first quarter of fiscal 2008. There was no material impact on our consolidated financial position, results of operations and cash flows as a result of adoption.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we adopted SFAS 157 in the first quarter of fiscal 2008. In February 2008, the FASB issued FASB Staff Position No. (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. On October 10, 2008, the FASB issued FSP FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies

Table of Contents

the application of SFAS 157 in a market that is not active and provides examples to illustrate key considerations in determining the fair value of the financial asset when the market for that financial asset is not active. Therefore, we adopted the provisions of SFAS 157 and FSP FAS 157-3 with respect to our financial assets and liabilities only. The FASB also issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115, (SFAS 159) in February 2007, which permits entities to choose to measure at fair value, at specified election dates, many financial instruments and certain other items that are not currently required to be measured at fair value. The statement does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS 159 is an elective standard which permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We have not elected the fair value option for any assets or liabilities under SFAS 159. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption of these pronouncements.

Liquidity and Capital Resources

As of December 31, 2008, we had \$43.4 million in cash, cash equivalents and marketable securities and \$25.1 million in investments held by SDI. Our funds are currently invested in a variety of securities, including highly liquid institutional money market funds, government agency securities and corporate obligations, some of which are government-secured.

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 over the prior year was due primarily to the reduction in our net loss for 2008. The improvement in net loss reflected the increase in revenues, in particular, revenue associated with the Merck collaboration for HEPLISAV. Cash used in operating activities during the year ended December 31, 2007 was \$32.0 million compared to \$37.2 million for the same period in 2006. The decrease in cash usage was due primarily to the receipt of \$31.5 million in upfront fees from our collaboration with Merck, offset by our net loss and the amount attributed to the noncontrolling interest in SDI.

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 used in investing activities during the year ended December 31, 2007 was \$3.6 million compared to \$20.4 million for the same period in 2006. The decrease in cash usage was primarily due to the \$14.0 million that was paid to acquire Rhein in 2006 as well as higher net proceeds from maturities of marketable securities in 2007.

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. Cash provided by financing activities during the year ended December 31, 2007 was \$35.7 million compared to \$62.9 million for the same period in 2006. Cash provided by financing activities in 2007 primarily included \$30 million in proceeds from the purchase of the noncontrolling interest in SDI and \$5.5 million in loan proceeds from Deerfield.

We currently anticipate that our cash and marketable securities, collaboration agreements, and investments held by SDI will enable us to maintain our operations for at least the next twelve months. Because of the significant time it will take for any of our product candidates to complete clinical trials, achieve regulatory approval and generate significant revenue, we will require substantial additional capital resources. We may raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations.

Table of Contents

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

Contractual Obligations

The following summarizes our significant contractual obligations as of December 31, 2008 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
Future minimum payments under our operating leases, excluding payments from the sublease agreement	\$ 19,714	\$ 2,400	\$ 7,890	\$ 4,724	\$ 4,700
Long-term liability from the program option exercised under the SDI collaboration	15,000		15,000		
Total	\$ 34,714	\$ 2,400	\$ 22,890	\$ 4,724	\$ 4,700

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 scheduled payments to us totaling \$56 thousand through 2008, \$58 thousand through 2009 and \$40 thousand thereafter until August 2010. The sublease rental income is offset against rent expense.

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

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2008 and 2007. 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, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of December 31, 2008.

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,

Table of Contents

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, 2008, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$3 million through 2010. 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, 2008, such fees and milestone payments to the Regents could approximate \$1 million in 2009.

Off-balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosure About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we currently maintain our portfolio of cash equivalents and investments in a variety of securities, including money market funds, government agency securities and corporate obligations, some of which are government-secured. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans. 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, 2008 was \$0.4 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

Table of Contents

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

<u>Report of Independent Registered Public Accounting Firm</u>	Page No. 47
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	48
<u>Consolidated Statements of Operations</u>	49
<u>Consolidated Statements of Stockholders' Equity</u>	50
<u>Consolidated Statements of Cash Flows</u>	51
<u>Notes to Consolidated Financial Statements</u>	52

Table of Contents

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, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

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, 2008, 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 4, 2009, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Francisco, California

March 4, 2009

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

	December 31,	
	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,103	\$ 14,293
Marketable securities	15,264	42,324
Investments held by Symphony Dynamo, Inc. (SDI)	25,109	31,631
Restricted cash	668	408
Accounts receivable	6,407	7,234
Prepaid expenses and other current assets	991	6,049
Total current assets	76,542	101,939
Property and equipment, net	9,510	7,314
Goodwill	2,312	2,312
Other intangible assets, net	2,259	3,239
Other assets		5,645
Total assets	\$ 90,623	\$ 120,449
Liabilities, noncontrolling interest and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 905	\$ 4,418
Accrued liabilities	6,816	12,059
Deferred revenues	33,133	3,427
Total current liabilities	40,854	19,904
Deferred revenues, noncurrent	18,512	40,792
Liability from program option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	101	5,622
Noncontrolling interest in SDI	2,634	8,341
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2008 and 2007		
Common stock: \$0.001 par value; 100,000 shares authorized at December 31, 2008 and 2007; 39,854 and 39,765 shares issued and outstanding at December 31, 2008 and 2007, respectively	40	40
Additional paid-in capital	262,579	258,266
Accumulated other comprehensive income (loss):		
Unrealized gain on marketable securities available-for-sale	49	138
Cumulative translation adjustment	(403)	260
Accumulated other comprehensive income (loss)	(354)	398
Accumulated deficit	(248,743)	(227,914)
Total stockholders' equity	13,522	30,790
Total liabilities, noncontrolling interest and stockholders' equity	\$ 90,623	\$ 120,449

See accompanying notes.

Table of Contents

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Collaboration revenue	\$ 31,666	\$ 9,315	\$ 1,557
Grant revenue	2,999	3,046	1,549
Service and license revenue	2,429	1,732	1,741
Total revenues	37,094	14,093	4,847
Operating expenses:			
Research and development	44,771	65,888	50,116
General and administrative	15,463	18,293	14,836
Acquired in-process research and development			4,180
Amortization of intangible assets	980	1,004	698
Total operating expenses	61,214	85,185	69,830
Loss from operations	(24,120)	(71,092)	(64,983)
Interest and other income	1,741	4,165	3,287
Loan forgiveness	5,000		
Interest expense	(9,157)	(1,719)	(99)
Loss including noncontrolling interest in SDI	(26,536)	(68,646)	(61,795)
Amount attributed to noncontrolling interest in SDI	5,707	8,675	9,743
Net loss	\$ (20,829)	\$ (59,971)	\$ (52,052)
Basic and diluted net loss per share	\$ (0.52)	\$ (1.51)	\$ (1.61)
Shares used to compute basic and diluted net loss per share	39,819	39,746	32,339

See accompanying notes.

Table of Contents

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock			Accumulated Other Comprehensive Income (Loss)				Stockholders Equity
	Shares	Par Amount	Additional Paid-In Capital	Deferred Stock Compensation		Accumulated Deficit		
Balances at December 31, 2005	30,482	\$ 30	\$ 192,840	\$ (2,467)	\$ (149)	\$ (115,891)	\$ 74,363	
Issuance of common stock upon equity offerings	8,794	9	44,032				44,041	
Exercise of stock options	412	1	1,339				1,340	
Issuance of common stock under Employee Stock Purchase Plan	27		114				114	
Issuance of warrants in conjunction with Symphony Dynamo, Inc. transaction			5,646				5,646	
Stock compensation expense			3,283				3,283	
Reclassification of deferred stock compensation balance upon adoption of FAS 123R			(2,467)	2,467				
Comprehensive loss:								
Change in unrealized gain on marketable securities					172		172	
Cumulative translation adjustment					149		149	
Net loss						(52,052)	(52,052)	
Comprehensive loss							(51,731)	
Balances at December 31, 2006	39,715	40	244,787		172	(167,943)	77,056	
Exercise of stock options	6		22				22	
Issuance of common stock under Employee Stock Purchase Plan	44		149				149	
Proceeds from issuance of common stock, net of fees			(19)				(19)	
Issuance of warrants in conjunction with Deerfield financing agreement			9,796				9,796	
Stock compensation expense			3,531				3,531	
Comprehensive loss:								
Change in unrealized gain on marketable securities					110		110	
Cumulative translation adjustment					116		116	
Net loss						(59,971)	(59,971)	
Comprehensive loss							(59,745)	
Balances at December 31, 2007	39,765	40	258,266		398	(227,914)	30,790	
Exercise of stock options	2		5				5	
Issuance of common stock under Employee Stock Purchase Plan	87		204				204	
Modification of warrants in conjunction with Deerfield financing agreement			899				899	
Stock compensation expense			3,205				3,205	
Comprehensive loss:								
Change in unrealized gain on marketable securities					(89)		(89)	
Cumulative translation adjustment					(663)		(663)	
Net loss						(20,829)	(20,829)	

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Comprehensive loss	(21,581)
--------------------	----------

Balances at December 31, 2008	39,854	\$	40	\$	262,579	\$	(354)	\$	(248,743)	\$	13,522
-------------------------------	--------	----	----	----	---------	----	-------	----	-----------	----	--------

See accompanying notes.

Table of Contents

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2008	2007	2006
Operating activities			
Net loss	\$ (20,829)	\$ (59,971)	\$ (52,052)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,850	1,483	1,130
Amount attributed to noncontrolling interest in SDI	(5,707)	(8,675)	(9,743)
Acquired in-process research and development			4,180
Amortization of intangible assets	980	1,004	698
(Gain) loss on disposal of property and equipment	32		(36)
Accretion and amortization on marketable securities	(721)	(1,855)	(296)
Realized loss on investments			23
Interest associated with Deerfield financing agreement	9,090	1,248	
Loan forgiveness	(5,000)		
Stock-based compensation expense	3,205	3,531	3,283
Changes in operating assets and liabilities:			
Accounts receivable	827	(5,080)	(976)
Prepaid expenses and other current assets	1,533	(1,851)	604
Inventory		257	(257)
Other assets	(79)	1,269	(513)
Accounts payable	(3,513)	2,237	1,006
Accrued liabilities	(6,129)	930	5,847
Deferred revenues	7,426	33,441	9,862
Net cash used in operating activities	(17,035)	(32,032)	(37,240)
Investing activities			
Change in investments held by SDI	6,522	(18,268)	(13,363)
Cash paid for acquisition, net of cash acquired			(14,045)
Purchases of marketable securities	(35,755)	(80,232)	(65,842)
Proceeds from maturities of marketable securities	59,401	98,550	63,008
Proceeds from sales of marketable securities	4,046		10,987
Purchases of property and equipment	(4,098)	(3,647)	(1,125)
Net cash provided by (used in) investing activities	30,116	(3,597)	(20,380)
Financing activities			
Proceeds from purchase of noncontrolling interest by shareholders in SDI, net of fees		30,000	17,405
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		(19)	44,041
Proceeds from exercise of stock options	5	22	1,340
Proceeds from employee stock purchase plan	204	149	114
Net cash provided by financing activities	1,392	35,652	62,900
Effect of exchange rate on cash and cash equivalents	(663)	116	149
Net increase in cash and cash equivalents	13,810	139	5,429
Cash and cash equivalents at beginning of year	14,293	14,154	8,725
Cash and cash equivalents at end of year	\$ 28,103	\$ 14,293	\$ 14,154

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Supplemental disclosure of cash flow information

Cash paid during the year for interest	\$	885	\$	356	\$
Non-cash activities:					
Liability from program option exercised under the SDI collaboration	\$		\$	15,000	\$
Warrants issued in conjunction with the SDI transaction	\$		\$		\$ 5,646
Warrants issued in conjunction with the Deerfield financing agreement	\$		\$	9,796	\$
Loan forgiveness	\$	5,000	\$		\$
Modification of warrants previously issued to Deerfield	\$	899	\$		\$
Disposal of fully depreciated property and equipment	\$		\$	238	\$ 395

See accompanying notes.

Table of Contents

DYNAVAX TECHNOLOGIES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) product candidates. Based on our proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. We have partnerships with leading pharmaceutical companies such as GlaxoSmithKline (GSK), AstraZeneca AB (AstraZeneca), and Novartis Vaccines and Diagnostics, Inc. (Novartis) as well as funding from Symphony Dynamo, Inc. (SDI) and the National Institutes of Health (NIH). 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 April 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, a wholly-owned subsidiary in Düsseldorf, Germany. Our wholly-owned subsidiary in Japan formed in December 2004, Ryden Therapeutics KK, was liquidated in the fourth quarter of 2006. Our wholly-owned subsidiary in Singapore formed in October 2003, Dynavax Asia Pte. Ltd., was liquidated in the fourth quarter of 2007.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries as well as the accounts of a variable interest entity, Symphony Dynamo, Inc. (SDI), which we consolidate pursuant to Financial Accounting Standards Board Interpretation No. 46 (revised 2003), Consolidation of Variable Interest Entities, or FIN 46R. All significant intercompany accounts and transactions have been eliminated. In accordance with SFAS No. 131, Disclosure About Segments of an Enterprise and Related Information, we are required to report operating segments and make related disclosures about our revenues and long-lived assets by geographic area. We operate in one business segment, which is the discovery and development of biopharmaceutical products. In fiscal years 2008, 2007 and 2006, respectively, 93%, 88% and 64% of our revenues were earned in the U.S. and the remaining revenues were earned in Europe. As of December 31, 2008 and 2007, respectively, 48% and 73% of our long-lived assets were located in the U.S. and the remaining assets were located in Europe.

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. Gains and losses resulting from currency transactions are included in the consolidated statements of operations.

Cash, Cash Equivalents, Marketable Securities and Investments held by Symphony Dynamo, Inc.

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,

Table of Contents

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.

Investments held by SDI consist of investments in money market funds. As of December 31, 2008, we had investments held by SDI of \$25.1 million.

We have classified our entire investment portfolio as available-for-sale. We view our available-for-sale portfolio as available for use in current operations, and accordingly, have classified all investments as short-term. As of December 31, 2008 the stated maturity of our investments is within one year of the current balance sheet date. In accordance with SFAS 115, Accounting for Certain Investments in Debt and Equity Securities, 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.

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.

Table of Contents

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.

Long-lived Assets

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* 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.

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 year ended December 31, 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 derive 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. In accordance with SAB 104, 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 collectibility is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under the provisions of EITF 00-21. 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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

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 the provisions of EITF 00-21, the total consideration received is grouped as one unit and the applicable revenue recognition methodology is applied to the single unit.

Table of Contents

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

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

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

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

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards. 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. Agreements entered into after January 1, 2008 are evaluated under the provisions of EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* which requires the Company to defer and capitalize costs related to non-refundable advance payments for good or services to be received in the future for use in research and development activity. The capitalized amounts are 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, and 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.

Acquired In-process Research and Development

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To determine the value of the acquired in-process research and development, or in-process R&D associated with the Rhein Biotech GmbH transaction discussed in Note 6, we used the income approach

Table of Contents

and the cost approach to value in-process research and development. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for distribution to the investors in the asset. We performed a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. The cost approach is based on the theory that a prudent investor would pay no more than the cost of constructing a similar asset of like utility at prices applicable at the time of the appraisal. We estimate the costs involved in re-creating the technology using the historical cost and effort applied to the development of the technology prior to the valuation date. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process R&D is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur.

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 purchase 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 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 as required by SFAS No. 142, Goodwill and Other Intangible Assets.

Consolidation of Variable Interest Entities

Under FIN 46R, 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.

Based on the provisions of FIN 46R, we have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Our consolidated financial statements include the accounts of Symphony Dynamo, Inc., a variable interest entity, of which we are the primary beneficiary, as discussed in Note 8.

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, Share-Based Payment, or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards. We have elected to adopt the

Table of Contents

alternative transition method provided in the FASB Staff Position for calculating the tax effects, if any, of stock-based compensation expense pursuant to FAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of FAS 123R.

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. 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 FAS 109, *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 of FIN 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109. FIN 48 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 of FIN 48, 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, 2007, 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. incomes 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, 2009.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure

Table of Contents

requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact of the adoption of SFAS 160 on our consolidated results of operations and financial condition. SFAS 160 could change our accounting for the noncontrolling interest in SDI, a variable interest entity which we consolidate. Under current accounting standards, we do not reduce the carrying value of the noncontrolling interest below zero. Under SFAS 160, the noncontrolling interest could have a negative carrying value. In addition, upon adoption, we plan to reclassify the noncontrolling interest, on our consolidated balance sheet from mezzanine to stockholders' equity.

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaboration Agreements*, which required certain income statement presentation of transactions with third parties and of payments between parties to the collaboration arrangement, along with disclosure about the nature of the arrangement. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated results of operations and financial condition.

In March 2007, the FASB discussed EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which addressed the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus was not permitted. Accordingly, we adopted EITF 07-3 in the first quarter of fiscal 2008. There was no material impact on our consolidated financial position, results of operations and cash flows as a result of adoption.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we adopted SFAS 157 in the first quarter of fiscal 2008. In February 2008, the FASB issued FASB Staff Position No. (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. On October 10, 2008, the FASB issued FSP FAS 157-3,

Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active, which clarifies the application of SFAS 157 in a market that is not active and provides examples to illustrate key considerations in determining the fair value of the financial asset when the market for that financial asset is not active. Therefore, we adopted the provisions of SFAS 157 and FSP FAS 157-3 with respect to our financial assets and liabilities only. The FASB also issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, (SFAS 159) in February 2007, which permits entities to choose to measure at fair value, at specified election dates, many financial instruments and certain other items that are not currently required to be measured at fair value. The statement does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS 159 is an elective standard which permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We have not elected the fair value option for any assets or liabilities under SFAS 159. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption of these pronouncements.

Table of Contents**3. Fair Value Measurements**

SFAS 157 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 SFAS 157 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 SFAS 157 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.

In accordance with SFAS 157, 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 December 31, 2008 (in thousands):

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

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, 2008 and 2007 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2008:				
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
Total	\$ 63,472	\$ 49	\$	\$ 63,521
December 31, 2007:				
Certificates of deposit and money market funds	\$ 42,290	\$	\$	\$ 42,290

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Corporate debt securities	44,684	140	(2)	44,822
Total	\$ 86,974	\$ 140	\$ (2)	\$ 87,112

There were immaterial realized gains from the sale of marketable securities for the year ended December 31, 2008 and no realized gain for the year ended December 31, 2007 and 2006. Realized losses from the sale of marketable securities were zero in 2008 and 2007 and immaterial in 2006. As of December 31, 2008 and 2007,

Table of Contents

all of our investments have a stated maturity date that is within one year of the current balance sheet date. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity. As of December 31, 2008, our marketable securities had the following maturities (in thousands):

	Amortized Cost	Estimated Fair Value
Maturities:		
Within 1 year	\$ 63,472	\$ 63,521
Total	\$ 63,472	\$ 63,521

5. Property and Equipment

Property and equipment as of December 31, 2008 and 2007 consist of the following (in thousands):

	December 31,	
	2008	2007
Laboratory equipment	\$ 15,433	\$ 12,824
Computer equipment	1,461	1,403
Furniture and fixtures	1,810	1,525
Leasehold improvements	3,593	2,810
	22,297	18,562
Less accumulated depreciation and amortization	(12,787)	(11,248)
Total	\$ 9,510	\$ 7,314

Depreciation and amortization expense on property and equipment was \$1.9 million, \$1.5 million and \$1.2 million for the years ended December 31, 2008, 2007, and 2006, respectively.

6. Acquisition of Rhein Biotech GmbH

On April 21, 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, from Rhein Biotech NV, a subsidiary of Berna Biotech AG, or Berna. As a result, the financial position and results of operations of Rhein have been included in our consolidated financial statements as of December 31, 2008 and 2007 and the period from April 21, 2006 through December 31, 2006. Rhein, located in Düsseldorf, Germany, became a wholly-owned subsidiary which we refer to as Dynavax Europe. Through this acquisition, we gained ownership of a certified current Good Manufacturing Practice, or GMP, vaccine manufacturing facility in the European Union, control over the production and supply of its hepatitis B surface antigen and potentially other antigens to support clinical and commercial programs, management and personnel with expertise in biopharmaceutical product development and production and a complementary pipeline of vaccine and antiviral products. Upon closing of the transaction, our license and supply agreement with Berna for the supply of hepatitis B surface antigen used in our HEPLISAV vaccine was terminated, eliminating Berna's option to commercialize HEPLISAV.

Under the terms of the transaction, we purchased all of the outstanding capital stock of Rhein, which included the satisfaction of outstanding debt and certain employee and acquisition costs for an aggregate purchase price of approximately \$14.6 million. The components of the purchase price are summarized in the following table (in thousands):

Consideration and acquisition costs:	
Cash paid for common stock	\$ 7,925
Cash paid to satisfy outstanding debt	4,550

Employee costs	745
Acquisition costs	1,338
Total purchase price	\$ 14,558

Table of Contents

Under the purchase method of accounting, the total purchase price is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of the acquisition. Certain purchase accounting adjustments were made in order to state the tangible assets acquired and liabilities assumed at their estimated fair values and in accordance with our accounting policies and U.S. generally accepted accounting principles. These adjustments primarily impacted deferred revenue and acquired property and equipment. We assessed the fair value of the identifiable intangible assets acquired, as well as in-process research and development. Our methodology for allocating the purchase price to in-process R&D was determined through established valuation techniques in the biotechnology industry. In-process R&D is expensed upon acquisition because technological feasibility had not been established at that date and no future alternative uses exist. The purchase price was allocated using information available at the time of acquisition. The excess of purchase price over the aggregate fair values was recorded as goodwill.

The allocation of the total purchase price is as follows (in thousands):

Allocation of purchase price:

Cash and cash equivalents	\$ 513
Accounts receivable	489
Other current assets	385
Property, plant and equipment	3,092
Goodwill	2,312
Intangible assets	5,080
In-process research and development	4,180
Accounts payable	(273)
Deferred revenue	(166)
Other current liabilities	(1,054)

Total purchase price \$ 14,558

Intangible assets consist primarily of manufacturing process, customer relationships, and developed technology. 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. The developed technology derives from a licensed hepatitis B vaccine product called Supravax, which was written off as an impairment charge in 2007. 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, 2008 and December 31, 2007 (in thousands, except years):

		December 31, 2008			December 31, 2007		
	Estimated Useful Life (In years)	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible Assets:							
Manufacturing process	5	\$ 3,670	\$ (1,978)	\$ 1,692	\$ 3,670	\$ (1,244)	\$ 2,426
Customer relationships	5	1,230	(663)	567	1,230	(417)	813
Developed Technology		180			180		
Total	5	\$ 5,080	\$ (2,641)	\$ 2,259	\$ 5,080	\$ (1,661)	\$ 3,239

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

Year ending December 31,

2009	980
2010	980

2011	299
Total	\$ 2,259

Table of Contents

A summary of the acquired in-process research and development programs, and of the value assigned and recognized as expense as of the acquisition date is as follows (in thousands):

Program	Description	Estimated Acquisition Date Fair Value
Supervax	A hepatitis B vaccine launched in Argentina in December 2006 and approved for marketing and sales through a third party distributor	\$ 890
Theravax	A potential therapy for treatment of chronic Hepatitis B infection	2,740
Cytovax	A potential prophylactic vaccine to prevent infection from cytomegalovirus	550
		\$ 4,180

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Supervax program was determined using the income approach, which discounts expected future cash flows to present value. We estimated the related future net cash flows between 2006 and 2020 and discounted them to their present value using a risk-adjusted discount rate of 50%, which was based on the estimated internal rate of return for Rhein's operations and was comparable to the estimated weighted average cost of capital for companies with Rhein's profile. The projected cash flows from the Supervax program were based on key assumptions such as estimates of revenues and operating profits related to the program considering its stage of development; the time and resources needed to complete the development and approval of the related product; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Given the high risk associated with the development of new drugs, we adjusted the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process.

From the acquisition date through the year ended December 31, 2006, we continued registration activities for Supervax in territories other than Argentina. Actual sales for the fiscal year ended 2006 of Supervax in Argentina, while immaterial, were substantially in accordance with the original projections at the valuation date. During fiscal year 2007, we continued to monitor sales of Supervax in Argentina and we continued efforts to market Supervax in order to determine if we could achieve planned regulatory approvals in other markets. We recorded immaterial revenues and expenses related to the manufacture and sale of formulated bulk vaccine in 2006 to the third party distributor. During the fourth quarter of 2007, we were notified that the distributor was unable to meet its annual commitment to order additional bulk vaccine due to its inability to sell all of the previously purchased Supervax product in the Argentine market. The underperformance of the Supervax program relative to originally expected future sales caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. As a result, we determined that estimated future cash flows from sales of Supervax were significantly less than the projection established at the time of acquisition, and we considered this an indicator of impairment. As of November 2007, we performed our impairment test of long-lived assets. Based on our analysis, the fair value of the Supervax developed technology and related inventory was estimated to be zero; therefore, we recorded a permanent write down of these assets in accordance with SFAS No. 144. 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 amounts of the intangible asset of \$0.1 million and the related inventory of \$0.3 million.

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Theravax and Cytovax programs was determined using the cost approach. We considered the stage of product development and the nature of these projects. At the valuation date, both Theravax and Cytovax were in early stages of development and were many years away from obtaining regulatory approval, if at all, and the risks associated with identifying material cash flows as well as the nature, timing and projected costs associated with the remaining efforts for completion of the projects were not reasonably estimable. However, we were able to

Table of Contents

estimate the cost involved in recreating the technology using historical data from Rhein, including cost and effort applied to the development of the technology prior to the acquisition date. We did not anticipate significant cash inflows for Theravax or Cytovax. Significant appraisal assumptions included historical data related to personnel effort, costs associated with those efforts, and external costs in order to estimate the fair value of these products as of the acquisition date.

In early 2007, we made a strategic decision to discontinue development of Cytovax in order to focus on other opportunities in our product pipeline; however, due to the early stage of development, there was no impact to our results of operations and financial condition. We intend to continue further development of our therapy to treat chronic hepatitis B infection, DV-601.

7. Current Accrued Liabilities

Current accrued liabilities as of December 31, 2008 and 2007 consist of the following (in thousands):

	December 31,	
	2008	2007
Payroll and related expenses	\$ 2,419	\$ 2,892
Legal expenses	1,387	1,708
Third party scientific research expense	1,730	6,044
Other accrued liabilities	1,280	1,415
Total	\$ 6,816	\$ 12,059

8. Symphony Dynamo, Inc.

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

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

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

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

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

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

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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

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

The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC (Holdings) and its wholly-owned subsidiary, Symphony Dynamo, Inc. (SDI). Pursuant to the Funding Agreement, Symphony invested \$50 million in Holdings (\$20 million at closing and an additional \$30 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing

Table of Contents

the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock, which Holdings distributed to Symphony, at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share if either of two events occurs: (a) we enter into a collaboration agreement with a third party for a specified oncology program; or (b) the Purchase Option is terminated or expires unexercised. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model and was recorded in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option (Purchase Option) to acquire the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices that range from \$84.2 million as of October 1, 2008, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The intellectual property rights to the remaining cancer and hepatitis C therapy programs, if not purchased through the exercise of the Purchase Option, will remain with SDI.

We have determined, pursuant to the guidance in FIN 46R, that SDI is a variable interest entity and we are its primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006.

At December 31, 2008, the investments held by SDI were \$25.1 million. The investments held by SDI in the consolidated balance sheet include the aggregate \$50 million of funding, less funds spent on the Development Programs as of the end of each reporting period.

At December 31, 2008, the noncontrolling interest balance was \$2.6 million. The noncontrolling interest in SDI in the consolidated balance sheet represents Symphony's equity investment in SDI of \$50 million, reduced by the \$5.6 million fair value of the warrants we issued and \$2.6 million of fees we paid to Symphony upon the transaction's closing, and the losses attributed to the noncontrolling interest since its inception in April 2006. The noncontrolling interest was further reduced when we recorded the \$15 million liability upon our exercise of the Program Option in April 2007, as that amount will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option.

Net losses incurred by SDI and charged to the noncontrolling interest were \$5.7 million and \$8.7 million for the year ended December 31, 2008 and 2007, respectively. In accordance with FIN 46R, we have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated statements of operations.

9. Financing 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 (Settlement Agreement) under which the parties agreed to terminate the Loan Agreement dated July 18, 2007 (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.

Table of Contents

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 VWAP in the 15-day period prior to achievement of certain milestones.

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

	Shares Issued	Expiration Date	Black-Scholes Assumptions Expected			Exercise Price per Share	Assigned Value using Black-Scholes
			Risk-Free Interest Rate	Life (in years)	Volatility		
Warrant Issuance Date:							
July 18, 2007	1,250	1/17/2013	4.9%	5.5	0.7	\$ 5.13	\$ 3,350
October 18, 2007	1,300	4/17/2013	4.2%	5.5	0.7	\$ 5.75	3,700
December 27, 2007	1,000	6/26/2013	3.6%	5.5	0.7	\$ 5.65	2,746
Total	3,550						\$ 9,796

At the date of each issuance, the warrant valuation was recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost was amortized on a straight-line basis and recognized as interest expense through the termination of the Loan Agreement. We amortized \$9.0 million and \$0.8 million of deferred transaction cost in interest expense for the years ended December 31, 2008 and 2007, 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 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:

	Shares Issued (in thousands)	Expiration Date	Exercise Price per Share
Warrant Issuance Date:			
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	700	2/26/2014	\$ 5.65 ⁽¹⁾
Total	3,550		

- (1) The warrants to purchase an aggregate of 700,000 shares of our common stock issued on December 27, 2007 were amended to provide for a termination date of February 26, 2014 at the existing exercise price of \$5.65 and if Dynavax's average daily volume weighted average price (VWAP) over the 15 trading days prior to August 26, 2009 is below \$4.00 per share then such warrants will be amended to provide

an exercise price equal to the VWAP over the 15 trading days prior to August 26, 2009.

Table of Contents

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 SFAS 123R, Share-Based Payment. We recorded interest expense and an increase of additional paid in capital of \$0.9 million for the fiscal year ended December 31, 2008 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 Berkeley Lease can be terminated in September 2009 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of December 31, 2008 and December 31, 2007. 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, 2008, 2007 and 2006, was \$2.5 million, \$2.1 million and \$1.8 million, respectively. Deferred rent was \$0.7 million as of December 31, 2008.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$56 thousand through 2008, \$58 thousand through 2009, and \$40 thousand thereafter 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, 2008, excluding payments from the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2009	2,400
2010	2,572
2011	2,629
2012	2,689
2013	2,734
Thereafter	6,690
Total	\$ 19,714

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, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2008 and December 31, 2007. 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, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of December 31, 2008.

Table of Contents

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, 2008, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$3 million through 2010. 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 \$1 million in 2009 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 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 and are eligible to receive future potential development and commercialization milestones totaling approximately \$200 million per program. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one product. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. For the year ended December 31, 2008, we recognized revenue of \$60 thousand related to the initial payment.

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, 2008 and 2007, we recognized revenue of \$5 million and \$0.4 million, respectively, related to the upfront fee. Collaboration revenue

Table of Contents

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 \$20.2 million and \$5.8 million for the years ended December 31, 2008 and 2007, respectively.

AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration. We received an upfront payment of \$10 million, and are eligible to receive research funding, preclinical milestone payments, and potential future development milestones of up to \$126 million. Upon commercialization, we are also eligible to receive royalties based on product sales. We are currently working on a second candidate drug, and in February 2009, we extended our research collaboration with AstraZeneca through July 2010 to provide funding for a third candidate drug.

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 year ended December 31, 2008, we recognized revenue of \$2.0 million related to the milestone for the nomination of a candidate drug. Collaboration revenue resulting from the performance of research services amounted to \$3.2 million and \$3.1 million for the years ended December 31, 2008, and 2007, respectively. As of December 31, 2008, we recorded deferred revenue of \$13 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 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 year ended December 31, 2008, we recognized revenue of approximately \$0.2 million.

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 year ended December 31, 2008, we recognized revenue of approximately \$0.4 million.

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 and \$0.2 million for the years ended December 31, 2007 and 2006, respectively.

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, 2008, 2007 and 2006, we recognized revenue of approximately \$3.0 million, \$3.0 million and \$1.3 million, respectively.

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

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss 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,		
	2008	2007	2006
Historical (in thousands, except per share amounts):			
Numerator:			
Net loss	\$ (20,829)	\$ (59,971)	\$ (52,052)
Denominator:			
Weighted-average common shares outstanding	39,819	39,746	32,340
Less: Weighted-average unvested common shares subject to repurchase			(1)
Denominator for basic and diluted net loss per share	39,819	39,746	32,339
Basic and diluted net loss per share	\$ (0.52)	\$ (1.51)	\$ (1.61)
Historical outstanding securities not included in diluted net loss per share calculation (in thousands):			
Options to purchase common stock	5,173	4,282	3,421
Warrants	5,550	5,550	2,084
	10,723	9,832	5,505

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

As of December 31, 2008, 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.

Table of Contents

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.

As of December 31, 2008, 5,100,000 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 option plans is set forth below:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2007	1,257,171	4,282,455	\$ 5.36
Options authorized	400,000		
Options granted	(2,199,700)	2,199,700	\$ 3.95
Options exercised			
1997 Plan options exercised		(1,833)	\$ 2.59
Options cancelled:			
Options forfeited (unvested)	1,035,547	(1,035,547)	\$ 5.37
Options expired (vested)	167,635	(167,635)	\$ 4.82
1997 Plan options expired (vested)		(104,164)	\$ 4.82
Balance at December 31, 2008	660,653	5,172,976	\$ 4.79

Employee Stock Purchase Plan

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

As of December 31, 2008, 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 193,868 shares of our common stock under the Purchase Plan. At December 31, 2008, 302,132 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"),

Table of Contents

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.

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		
	2008	2007	2006	2008	2007	2006
Weighted-average fair value	\$ 2.29	\$ 3.53	\$ 4.04	\$ 0.93	\$ 1.96	\$ 2.28
Risk-free interest rate	2.7%	4.7%	4.7%	2.4%	4.6%	4.9%
Expected life (in years)	4.4	4.5	5.6	1.3	1.2	1.2
Volatility	0.8	0.8	0.8	0.8	0.7	0.7

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 2008, 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.

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

	Years Ended December 31,		
	2008	2007	2006
Employees and directors stock-based compensation expense	\$ 3,183	\$ 3,462	\$ 3,153
Non-employees stock-based compensation expense	22	69	130
Total	\$ 3,205	\$ 3,531	\$ 3,283

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, 2008 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, 2008, the total unrecognized compensation cost related to non-vested options granted amounted to \$5.1 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.5 years.

Total options exercised during the years ended December 31, 2008, 2007 and 2006 were 1,833, 5,666 and 411,985, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2008, 2007 and 2006 was approximately \$6 thousand, \$6 thousand and \$1.3 million, respectively. No income tax benefits have been realized by us in 2008, 2007 and 2006, as we reported a net loss in each year.

Table of Contents

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, 2008:

	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)	4,632,030	\$ 4.84	7.3	\$
Options exercisable	2,536,286	\$ 5.09	6.3	\$

Prior to January 1, 2006, we accounted for our stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, Accounting for Stock Issued to Employees, or APB 25, and related interpretations, as permitted by FASB Statement No. 123, Accounting for Stock-Based Compensation, or FAS 123. On January 1, 2006, we adopted the fair value recognition provisions of FAS 123R using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

As a result of the adoption of FAS 123R, we reduced our deferred stock compensation balance and additional paid in capital previously associated with APB 25 accounting by \$2.5 million as of January 1, 2006.

14. Employee Benefit Plan

Effective September 1997, we adopted the Dynavax Technologies Corporation 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,		
	2008	2007	2006
U.S.	\$ (19,265)	\$ (58,521)	\$ (59,862)
Non U.S.	(1,564)	(1,450)	(1,933)
Total	\$ (20,829)	\$ (59,971)	\$ (61,795)

No income tax expense was recorded for the years ended December 31, 2008, 2007 and 2006 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):

	2008	2007	2006
Income tax benefit at federal statutory rate	\$ (7,082)	\$ (20,390)	\$ (21,045)
State tax	(1,601)	(2,600)	(3,852)
Unbenefitted foreign losses			(269)
Tax credits	(672)	(2,594)	(3,088)
Deferred compensation charges	503	495	(534)
In-process research and development			1,421

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Change in valuation allowance	13,792	20,680	27,391
Change in foreign tax rates		1,966	
Change in NOL	(4,810)	2,356	
Other	(130)	87	(24)
	\$	\$	\$

Table of Contents

Deferred tax assets and liabilities as of December 31, 2008 and 2007 consist of the following (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Net operating loss carry forwards	\$ 64,967	\$ 63,406
Research tax credit carry forwards	10,517	9,328
Accruals and reserves	3,483	7,067
Capitalized research costs	8,108	8,789
Deferred Revenue	14,788	
Other	2,431	2,279
	104,294	90,869
Less valuation allowance	(103,431)	(89,640)
Total deferred tax assets	\$ 863	\$ 1,229
Deferred tax liabilities:		
Other		
Acquired intangible assets.	(863)	(1,229)
Total deferred tax liabilities	\$ (863)	\$ (1,229)
Net deferred tax assets	\$	\$

SFAS 109 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. Accordingly, a full valuation allowance has been recorded for the net deferred tax assets at December 31, 2008 and 2007. The valuation allowance increased by \$13.8 million, \$20.7 million and \$27.4 million during the years ended December 31, 2008, 2007 and 2006, 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, 2008, 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. Currently there are no undistributed earnings in the foreign subsidiary as it has current and cumulative losses and thus no deferred tax liability would be necessary.

As of December 31, 2008, we had federal net operating loss carryforwards of approximately \$156.1 million, which will expire in the years 2011 through 2028 and federal research and development tax credits of approximately \$6.2 million, which expire in the years 2018 through 2028. Of these net operating losses, approximately \$25.6 million are attributable to Symphony Dynamo, Inc., which expire in the years 2026 through 2028.

As of December 31, 2008, we had net operating loss carryforwards for California state income tax purposes of approximately \$83.6 million, which expire in the years 2012 through 2028, and California state research and development tax credits of approximately \$6.5 million which do not expire.

As of December 31, 2008, we had net operating loss carryforwards for foreign income tax purposes of approximately \$19.3 million, which do not expire.

Table of Contents

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. FIN 48 had no impact on the reported carryforwards at December 31, 2007 and 2008.

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

	Year Ended December 31, 2008				Year Ended December 31, 2007			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 6,314	\$ 9,978	\$ 8,857	\$ 11,945	\$ 1,984	\$ 1,800	\$ 1,014	\$ 9,295
Net income (loss)	\$ (12,429)	\$ (6,079)	\$ (5,420)	\$ 3,099	\$ (13,090)	\$ (17,704)	\$ (17,101)	\$ (12,076)
Basic net income (loss) per share	\$ (0.31)	\$ (0.15)	\$ (0.14)	\$ 0.08	\$ (0.33)	\$ (0.45)	\$ (0.43)	\$ (0.30)
Weighted-average shares used in computing basic net income (loss) per share	39,785	39,806	39,831	39,854	39,727	39,741	39,753	39,765
Diluted net income (loss) per share	\$ (0.31)	\$ (0.15)	\$ (0.14)	\$ 0.08	\$ (0.33)	\$ (0.45)	\$ (0.43)	\$ (0.30)
Weighted-average shares used in computing diluted net income (loss) per share	39,785	39,806	39,831	39,854	39,727	39,741	39,753	39,765

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 Chief 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 Chief Financial Officer, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Chief 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, 2008. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an attestation report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

Table of Contents

Report of Independent Registered Public Accounting Firm

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, 2008, 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, 2008 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2008 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 4, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP
San Francisco, California

March 4, 2009

(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.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled Proposal One Elections of Directors, Executive Compensation, and Section 16(a) Beneficial Ownership Reporting Compliance in our Definitive Proxy Statement in connection with the 2009 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, 2008.

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, Chief Financial Officer, Chief Accounting 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: Deborah A. Smeltzer, 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

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

76

Table of Contents

2. Financial Statement Schedules

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

(b) Exhibits

Exhibit Number	Document
3.1(1)	Sixth Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
3.3(2)	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
4.1(3)	Registration Rights Agreement
4.2(3)	Form of Warrant
4.3(4)	Form of Specimen Common Stock Certificate
4.4(2)	Rights Agreement dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC
4.5(2)	Form of Rights Certificate
4.6	Form of Restricted Stock Unit Award Agreement.
10.32 (5)	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
10.33 (6)	Loan Agreement, dated July 18, 2007, between Deerfield Private design Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Special Situations Fund International Limited and Deerfield Private Design International. L.P., and Dynavax Technologies Corporation
10.34(7)	Merck Exclusive License and Development Collaboration Agreement, dated October 31, 2007
10.35(7)	Merck Manufacturing Agreement, dated October 31, 2007
10.36(8)	Amendment No. 1 to Common Stock Purchase Agreement, dated February 22, 2008, between Azimuth Opportunity Ltd., and Dynavax Technologies Corporation
10.37	Amended Management Continuity Agreement, dated as of October 3, 2008, between Dynavax Technologies Corporation and Dino Dina
10.38	Form of Amended Management Continuity Agreement between Dynavax Technologies Corporation and each of its executive officers
10.39	Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and Dynavax Technologies Corporation
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 Chief 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 Chief 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).

Table of Contents

- (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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, as filed with the SEC.
- (7) 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, 2007, 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 March 31, 2008, as filed with the SEC.

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.

Table of Contents

SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

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

President and Chief Executive Officer

(Principal Executive Officer)

Date: March 6, 2009

By: /s/ DEBORAH A. SMELTZER
Deborah A. Smeltzer

Vice President, Operations and

Chief Financial Officer

(Principal Financial Officer)

Date: March 6, 2009

Signature	Title	Date
/s/ DINO DINA, M.D. Dino Dina, M.D.	President and Chief Executive Officer (Principal Executive Officer)	March 6, 2009
/s/ DEBORAH A. SMELTZER Deborah A. Smeltzer	Vice President, Operations and Chief Financial Officer (Principal Financial Officer)	March 6, 2009
/s/ ARNOLD ORONSKY, Ph.D. Arnold Oronsky, Ph.D.	Chairman of the Board	March 6, 2009
/s/ NANCY L. BUC Nancy L. Buc	Director	March 6, 2009
Dennis Carson, M.D.	Director	
/s/ DENISE M. GILBERT, Ph.D. Denise M. Gilbert, Ph.D.	Director	March 6, 2009

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

David M. Lawrence, M.D.	Director	
/s/ PEGGY V. PHILLIPS Peggy V. Phillips	Director	March 6, 2009
/s/ STANLEY A. PLOTKIN, M.D. Stanley A. Plotkin, M.D.	Director	March 6, 2009