

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 17, 2008

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, 2007**
- 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: 000-50577**

**Dynavax Technologies Corporation**  
*(Exact name of registrant as specified in its charter)*

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

**33-0728374**  
*(IRS Employer  
Identification No.)*

**2929 Seventh Street, Suite 100  
Berkeley, CA 94710-2753  
(510) 848-5100**

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

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

**Title of Each Class:**

**Name of Each Exchange on Which Registered:**

None

None

**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, 2007 as reported on the Nasdaq Global Market, was approximately \$161,011,098. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 29, 2008, the registrant had outstanding 39,803,907 shares of common stock.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2008 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

---

**INDEX**

**DYNAVAX TECHNOLOGIES CORPORATION**

**Page No.**

**PART I**

<u>Item 1.</u>	<u>BUSINESS</u>	3
<u>Item 1A.</u>	<u>RISK FACTORS</u>	18
<u>Item 1B.</u>	<u>UNRESOLVED STAFF COMMENTS</u>	29
<u>Item 2.</u>	<u>PROPERTIES</u>	29
<u>Item 3.</u>	<u>LEGAL PROCEEDINGS</u>	29
<u>Item 4.</u>	<u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	29

**PART II**

<u>Item 5.</u>	<u>MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	30
<u>Item 6.</u>	<u>SELECTED FINANCIAL DATA</u>	32
<u>Item 7.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	33
<u>Item 7A.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	49
<u>Item 8.</u>	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	50
<u>Item 9.</u>	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	77
<u>Item 9A.</u>	<u>CONTROLS AND PROCEDURES</u>	77
<u>Item 9B.</u>	<u>OTHER INFORMATION</u>	78

**PART III**

<u>Item 10.</u>	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	79
<u>Item 11.</u>	<u>EXECUTIVE COMPENSATION</u>	79
<u>Item 12.</u>	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	79
<u>Item 13.</u>	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	79
<u>Item 14.</u>	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	79

**PART IV**

<u>Item 15.</u>	<u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	79
	<u>SIGNATURES</u>	82

- EXHIBIT 10.34
- EXHIBIT 10.35
- EXHIBIT 21.1
- EXHIBIT 23.1
- EXHIBIT 31.1
- EXHIBIT 31.2
- EXHIBIT 32.1
- EXHIBIT 32.2



**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. 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 is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent infectious diseases, allergies, cancer and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

Our product candidates include: HEPLISAV<sup>(tm)</sup>, a hepatitis B vaccine in Phase 3 partnered with Merck & Co. Inc.; TOLAMBA<sup>(tm)</sup>, a ragweed allergy therapy in Phase 2; a therapy for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca AB. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer and hepatitis C therapeutic programs. Deerfield Management, a healthcare investment fund, and its affiliates (Deerfield), have committed funding for our allergy programs.

**Recent Developments**

***HEPLISAV***

HEPLISAV, our product candidate for hepatitis B prophylaxis, is based on proprietary ISS that specifically targets TLR9 to stimulate an innate immune response. HEPLISAV combines ISS with hepatitis B surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection.

## **Table of Contents**

Previously reported clinical trial results have shown 100% seroprotection after two doses in subjects 18 to 39 years of age, and after three doses in difficult-to-immunize subjects 40 to 70 years of age.

We recently announced that two Investigational New Drug (IND) applications for HEPLISAV have been placed on clinical hold by the U.S. Food and Drug Administration (FDA) due to a serious adverse event (SAE) that occurred in one subject who received HEPLISAV in a Phase 3 study being conducted outside the United States. The subject was preliminarily diagnosed to have Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed. All subjects in this Phase 3 clinical study have received all doses per the study protocol, and will continue to be monitored. Administration of vaccine has been suspended in the only study of HEPLISAV where injections were being administered actively, a fully enrolled Phase 2 study in End Stage Renal Disease (ESRD) subjects being conducted in Canada. A total of approximately 2,500 individuals have been vaccinated with more than 5,000 doses of HEPLISAV in 10 clinical trials spanning approximately seven years. No additional HEPLISAV clinical trials will be initiated until the clinical hold has been resolved. We and Merck & Co., Inc. (Merck), along with additional collaborators, including clinical investigators and leading experts, are investigating the medical history of the individual who experienced the SAE to understand better the onset of this diagnosed disease, including whether it was a pre-existing condition. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development, or that if HEPLISAV continues in development, that the FDA will not require significant limitations impacting the timing and clinical data required to achieve approval.

In October 2007, we entered into a global license and development collaboration agreement with Merck to jointly develop HEPLISAV. 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 an initial upfront payment of \$31.5 million, and will be eligible to receive development cost reimbursement, future development and sales milestone payments up to \$105 million, and double-digit tiered royalties on global sales of HEPLISAV. Under Merck's oversight, we continue to manage the ongoing Phase 3 study in Canada and Europe as well as other licensure-required studies. The United States Food and Drug Administration Biologics Licensing Application (BLA) and other marketing applications will be the joint responsibility of Merck and Dynavax, and are intended to be submitted by Merck. Also in October 2007, we entered into a manufacturing agreement with Merck. We are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility using our proprietary technology developed there and later, at our expanded facility to support expected market demand. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development. Merck may terminate the agreement upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA is released.

## ***Allergy Franchise***

### ***TOLAMBA***

TOLAMBA, our product candidate for the treatment of ragweed allergy, consists of ISS linked to the purified major allergen of ragweed, Amb a 1. TOLAMBA is designed to target the underlying cause of seasonal allergic rhinitis caused by ragweed. The linking of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy.

In October 2007, we began dosing of TOLAMBA in subjects as part of an environmental exposure chamber study. Subjects were screened based on a history of ragweed allergy and a positive skin test. Exposure to ragweed allergen in the chamber is being used to select those individuals with confirmed ragweed allergic disease and establish their



baseline level of symptoms. Subjects are being treated and will be re-exposed in the chamber to determine the effect of the six-week, six-injection TOLAMBA regimen as compared to placebo. Data from this study are expected in the first half of 2008 and, if positive, we intend to initiate a pivotal field study to support a potential BLA submission.

## **Table of Contents**

### ***Peanut and Cat Allergy Therapies***

Our peanut and cat allergy programs involve direct linkage of certain allergens to a proprietary TLR9 agonist. This approach is designed to mask the IgE binding sites of the native allergen to ensure safety and to induce an allergen-specific Th1 to Th2 immune shift to reprogram the immune response in allergic patients. Preclinical proof of concept studies have been generated with our peanut allergy approach, which provided protection in a mouse model of peanut induced anaphylaxis. We anticipate that the clinical development path for a disease-modifying peanut and cat allergy therapies to be focused on established challenge studies, in which both patient selection and study timing can be tightly controlled.

In July 2007, Deerfield and its affiliates committed up to \$30 million in project financing for a chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs.

### ***Influenza Vaccine***

We are developing a universal flu vaccine designed specifically to overcome the limitations of standard seasonal and pandemic vaccines. Our approach combines standard flu vaccine, required for generating neutralizing antibodies against matched strains, with conserved antigens (NP and M2e) conjugated to a proprietary ISS. The ISS component enhances the immune response to standard vaccine, potentially increasing the efficacy and reducing the amount of antigen required. The conserved antigens enable protection against mismatched and pandemic strains, regardless of which strain ultimately causes a pandemic. This is a key differentiator versus other pandemic vaccines, most of which specifically target an individual H5 or H9 strain that may not ultimately acquire the characteristics of a potentially pandemic strain.

In August 2007, we were awarded a two-year \$3.25 million grant from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), to continue development of our universal influenza vaccine. The new grant is directed toward advancing preclinical research into IND-enabling studies and product development.

### **The Immune System**

The immune system is the body's natural defense mechanism against infectious pathogens, 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 against any foreign substance is a specialized function called innate immunity, which serves as a rapid response that protects the body during the days or weeks needed for a second longer-term immune response, termed adaptive immunity, to develop. Unique cells called dendritic cells have two key functions in the innate immune response. They produce molecules called cytokines that contribute to the killing of viruses and bacteria. In addition, they ensure that pathogens and other foreign substances are made 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 pathogens or offending substances and are able to guide the immune system to make the most appropriate type of response. When viruses, bacteria and abnormal cells such as cancer cells are encountered, dendritic cells trigger a Th1 response, whereas detection of a parasite infection leads dendritic cells to initiate a Th2 response. Th1 and Th2 responses last for extended periods of time in the form of Th1 and Th2 memory cells, conferring long-term immunity.

## **Table of Contents**

The diagram above is a visual representation of how the immune system reacts when it encounters antigen. Upon encountering antigen, a cascade of events is initiated that leads to either a Th1 or a Th2 immune response, as described more fully in the paragraphs above.

The Th1 response involves the production of specific cytokines, including interferon-alpha, interferon-gamma and interleukin 12, or IL-12, as well as the generation of killer T cells, a specialized immune cell. These cytokines and killer T cells are believed to be the body's most potent anti-infective weapons. 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 period of time in the form of memory Th1 cells, even if the antigen or allergen target is eliminated. If another infection by the same pathogen occurs, the immune system is able to react more quickly and powerfully to the infection, because the memory Th1 cells can reproduce immediately. When the Th1 response to an infection is insufficient, chronic disease can result. When the Th1 response is inappropriate, diseases such as rheumatoid arthritis can result, in part from elevated levels of Th1 cytokines.

Activation of the Th2 response results in the production of other cytokines, IL-4, IL-5 and IL-13. These cytokines attract inflammatory cells such as eosinophils, basophils and mast cells capable of destroying the invading organism. In addition, the Th2 response leads to the production of a specialized antibody, IgE. IgE has the ability to recognize foreign antigens and allergens and further enhances the protective response. An inappropriate activation of the Th2 immune response to allergens, such as plant pollens, can lead to chronic inflammation and result in allergic rhinitis, asthma and other allergic diseases. This inflammation is sustained by memory Th2 cells that are reactivated upon subsequent exposures to the allergen, leading to a chronic disease.

## **ISS and the Immune System**

Our principal product development efforts are based on a technology that uses short synthetic DNA molecules called ISS that stimulate a Th1 immune response while suppressing Th2 immune responses. ISS contain specialized sequences that activate the innate immune system. ISS are recognized by a specialized subset of dendritic cells containing a unique receptor called Toll-Like Receptor 9, or TLR9. The interaction of TLR9 with ISS triggers the biological events that lead to the suppression of the Th2 immune response and the enhancement of the Th1 immune response.

## **Table of Contents**

We believe ISS have the following benefits:

ISS work by changing or reprogramming the immune responses that cause disease rather than just treating the symptoms of disease.

ISS influence helper T cell responses in a targeted and highly specific way by redirecting the response of only those T cells involved in a given disease. As a result, ISS do not alter the ability of the immune system to mount an appropriate response to infecting pathogens. In addition, because TLR9 is found only in a specialized subset of dendritic cells, ISS do not cause a generalized activation of the immune system, which might otherwise give rise to an autoimmune response.

ISS, in conjunction with an allergen or antigen, establish populations of memory Th1 cells, allowing the immune system to respond appropriately to each future encounter with a specific pathogen or allergen, leading to 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 Allergens**

We link ISS to allergens that are known to cause specific allergies. By chemically linking ISS to allergens, rather than simply mixing them, we generate a superior Th1 response due to the fact that the ISS and allergen are presented simultaneously to the same part of the immune system. The linked molecules generate an increased Th1 response by the immune system in the form of IgG antibodies and interferon-gamma. In addition, the ISS-linked allergens have a highly specific and potent inhibitory effect on the Th2 cells, thereby reprogramming the immune response away from the Th2 response that causes specific allergies. Upon subsequent natural exposure to the allergens, the Th1 memory response is triggered and may provide long-term suppression of allergic responses.

### **ISS Linked to or Combined with Antigens**

We also link ISS to antigens associated with pathogens such as viruses and bacteria to stimulate an immune response that will attack and destroy infected or abnormal cells. ISS, linked to or combined with appropriate antigens, increase the visibility of the antigen to the immune system and induce a highly specific and enhanced Th1 response, including increased IgG antibody production. As with ISS linked to allergens, this treatment also generates memory T cells that confer long-term protection against specific pathogens. This treatment may also have the potential for synergy with other cancer or infectious disease therapies.

### **ISS Alone**

We use ISS alone in diseases like asthma, where a large variety of allergens may be associated with an inappropriate immune response. ISS administered alone may suppress the Th2 inflammatory response caused by any number of allergens, modifying the underlying cause of inflammation, as well as providing symptomatic relief. ISS may also be used in conjunction with a variety of anti-tumor monoclonal antibodies and chemotherapy agents as a combination therapy, with the goal of stimulating the elimination of cancer cells.

### **Advanced ISS Technologies**

We have developed proprietary technologies that modify the molecular structure of ISS to significantly increase its versatility and potency. We are using these technologies in most of our preclinical programs and believe that they will be essential to our future product development efforts. Our advanced ISS technologies include ISS-like compounds, which we call CICs, as well as advanced ISS formulations.

CICs are molecules that are a mixture of nucleotide and non-nucleotide components. We have identified optimal sequences that induce particular immune responses, including potent interferon-alpha induction. CICs

## **Table of Contents**

can be tailored to have specific immunostimulatory properties and can be administered alone, or linked to allergens or antigens.

We have also developed formulations for ISS and CICs that may dramatically increase their potency. These advanced formulations can be used in situations where high potency is required to see a desired clinical outcome and can decrease the dosage of ISS or CICs required to achieve therapeutic effect.

### **Our Primary Development Programs**

Our primary development programs are HEPLISAV, Allergy and Influenza.

#### ***HEPLISAV: Our Hepatitis B Vaccine Candidate***

Current hepatitis B vaccines consist of hepatitis B surface antigen combined with alum as an adjuvant. HEPLISAV is composed of hepatitis B surface antigen combined with 1018 ISS and, unlike conventional three-dose vaccines, appears to require only two vaccinations over one month to achieve protective hepatitis B antibody responses in healthy young adults. In addition, clinical studies have demonstrated that HEPLISAV offers higher levels of immunity in the age 40-70 population, which responds poorly to current vaccines. In October 2007, we entered into a global license and development collaboration agreement with Merck to jointly develop HEPLISAV.

#### ***Clinical Status***

Our ongoing multi-center Phase 3 pivotal trial known as PHAST (Phase 3 HEPLISAV Short-regimen Trial), which began in Canada in late 2006 and in Germany in June 2007, has been placed on clinical hold by the FDA as a precautionary matter due to a serious adverse event (SAE) that occurred in one subject who received HEPLISAV. The study had enrolled over 2,400 subjects 11 to 55 years of age, and was designed to compare a two-dose regimen of HEPLISAV (administered at 0 and 1 month) to the conventional three-dose regimen of Engerix-B<sup>®</sup> marketed by GlaxoSmithKline (administered at 0, 1 and 6 months).

In June 2007, we initiated a safety and immunogenicity study in the U.S. Consistent with the PHAST trial, subjects 11 to 55 years of age received a two-dose regimen of HEPLISAV, at 0 and 1 month. This safety study is designed to enable further clinical development in the U.S.

Pending assessment of the SAE in the PHAST trial, we placed on hold an ongoing Phase 2 trial initiated in August 2007 in Canada in patients with ESRD to evaluate the safety and immunogenicity of two different doses of HEPLISAV. The trial had enrolled adults 40 to 70 years of age who have progressive loss of renal function and are either pre-dialysis or hemodialysis patients. This is a difficult-to-immunize patient population for whom conventional hepatitis B vaccines have shown limited efficacy.

Results from Phase 2 and Phase 3 trials showed that HEPLISAV was well tolerated and induced more rapid immunity with fewer vaccinations in both healthy young and older adults than GlaxoSmithKline's Engerix-B. We conducted a Phase 2 trial in Canada evaluating the immunogenicity of two doses of HEPLISAV compared to Engerix-B. A total of 99 healthy young adults were enrolled in this study, randomized to our vaccine or Engerix-B. Results showed that HEPLISAV induced a 79% rate of protective hepatitis B antibody response after one dose and protective hepatitis B antibody response in 100% of recipients after the second dose at two months. In contrast, subjects receiving Engerix-B had protective hepatitis B antibody responses after the first and second doses in 12% and 64% of recipients, respectively.

We completed a Phase 3 trial in Singapore, Korea and the Philippines that evaluated the immunogenicity of our vaccine in older subjects (ages 40-70 years) who have a diminished ability to respond to current vaccines. Results showed superiority of HEPLISAV compared to Engerix-B relative to the primary efficacy endpoint of seroprotection (100% seroprotection in the HEPLISAV-vaccinated group compared to 73.1% in the Engerix-B-vaccinated group). Results also showed that subjects vaccinated with HEPLISAV experienced more durable seroprotection. At week 50, the HEPLISAV-vaccinated group retained 100% seroprotection compared to 68.6% for the Engerix-B-vaccinated group. The primary endpoint of the trial was seroprotection following three doses. The safety profile of HEPLISAV was comparable to Engerix-B.

## **Table of Contents**

### ***Commercial Opportunity***

Hepatitis B is a common chronic infectious disease with an estimated 350 million chronic carriers worldwide. Prevention of hepatitis caused by HBV is central to managing the spread of the disease, particularly in regions of the world with large numbers of chronically infected individuals. While many countries have instituted infant vaccination programs, compliance is not optimal. Moreover, a large number of individuals born prior to the implementation of these programs are unvaccinated and are at risk for the disease. In addition, not all individuals respond to currently approved vaccines. Annual sales of hepatitis B vaccines are approximately \$1.0 billion globally.

In October 2007, we entered into a global license and development collaboration agreement with Merck to jointly develop HEPLISAV. 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 an initial upfront payment of \$31.5 million, and will be eligible to receive development cost reimbursement, future development and sales milestone payments up to \$105 million, and double-digit tiered royalties on global sales of HEPLISAV. Under Merck's supervision, we continue to manage the ongoing Phase 3 study in Canada and Europe as well as other licensure-required studies. The United States Food and Drug Administration Biologics Licensing Application (BLA) and other marketing applications will be the joint responsibility of Merck and Dynavax, and are intended to be submitted by Merck. Also in October 2007, we entered into a manufacturing agreement with Merck. We are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility using our proprietary technology developed there and later, at our expanded facility to support expected market demand. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development. Merck may terminate the agreement upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA is released.

### **Allergy Franchise**

#### ***TOLAMBA for Ragweed Allergy***

TOLAMBA consists of 1018 ISS linked to the purified major allergen of ragweed called Amb a 1. TOLAMBA may target the underlying cause of seasonal allergic rhinitis caused by ragweed and offers a six-week treatment regimen potentially capable of providing long-lasting therapeutic results. The linking of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect. Preclinical data suggest that Th2 cells responsible for inflammation associated with ragweed allergy are suppressed, leading to reprogramming of the immune response away from the Th2 response and toward a Th1 memory response so that, upon subsequent natural exposure to the ragweed allergen, long-term immunity is achieved.

#### ***Clinical Status***

To date, TOLAMBA has been administered to over 1,100 patients, and has been safe and well-tolerated. A Phase 2 study conducted in 2001-2002 showed 55% reduction ( $p=0.03$ ) in total nasal symptom scores (TNSS) in the first season which was maintained ( $p=0.02$ ) in the second season with no additional therapy (*NEJM Oct 2006, 355:14*). This was a single site study with well-characterized, severe allergic patients. The Phase 2 study conducted in 2004-2005 at 19 centers in the U.S. showed a 21% reduction in symptoms in the first year ( $p=0.04$ ) which was also maintained in the second year with no additional therapy ( $p=0.02$ ). However, the largest study of TOLAMBA (the DARTT study), conducted in 2006 in 738 patients at 30 U.S. sites, failed to enroll patients with measurable ragweed-allergic disease; therefore, the effect of the treatment could not be measured and the study did not achieve its primary endpoints. A pre-specified regional analysis demonstrated that sites in the Midwest comprising over half the



DARTT study population did include patients with more pronounced ragweed symptoms. In this group, the therapeutic benefit of TOLAMBA in reducing total nasal symptom scores was evident, as reflected in a clinically meaningful reduction of TNSS in

## **Table of Contents**

the treated patients. The data provided a rationale for continuing to evaluate our TLR9-based approach for treating ragweed and other allergic diseases.

In October 2007, we began dosing of TOLAMBA in subjects as part of an environmental exposure chamber study. Subjects were screened based on a history of ragweed allergy and a positive skin test. Exposure to ragweed allergen in the chamber is being used to select those individuals with confirmed ragweed allergic disease and establish their baseline level of symptoms. Subjects are being treated and will be re-exposed in the chamber to determine the effect of the six-week, six-injection TOLAMBA regimen as compared to placebo. Data from this study are expected in the first half of 2008 and, if positive, we intend to initiate a pivotal field study to support a potential BLA submission.

### ***Commercial Opportunity***

Medical management of seasonal allergic rhinitis is a multibillion-dollar global market. In the U.S. alone, approximately 50-60 million people (15-20% of the population) suffer from allergic rhinitis. The market for prescription interventions for allergic rhinitis was \$9 billion in 2007. Ragweed is the single most common seasonal allergen, affecting approximately 50% of those with allergic rhinitis, or 30 million Americans. Current treatment of allergic rhinitis includes prescription and over-the-counter (OTC) pharmacotherapies such as antihistamines, corticosteroids, leukotriene antagonists and decongestants. Although currently available pharmacotherapies may provide temporary symptomatic relief, they can be inconvenient to use and can cause side effects. In addition, these pharmacotherapies need to be administered chronically and do not modify the underlying disease state.

Allergy shots, or immunotherapy, are employed to alter the underlying immune mechanisms that cause allergic rhinitis. Conventional immunotherapy is a gradual immunizing process in which pollen extracts are mixed by the allergist and administered to induce increased tolerance to natural allergen exposure. The treatment regimen generally consists of weekly injections over the course of six months to a year, during which the dosing is gradually built up to a therapeutic level so as not to induce a severe allergic reaction. Once a therapeutic dosing level is reached, individuals then receive bi-weekly or monthly injections to build and maintain immunity over another two to four years. A patient typically receives between 60 and 90 injections over the course of treatment. Adverse reactions to conventional allergy immunotherapy are common and can range from minor swelling at the injection site to systemic reactions, and, in extremely rare instances, death. Other major drawbacks from the patients' perspective include the inconvenience of repeated visits to doctors' offices for each injection, the time lag between the initiation of the regimen and the reduction of symptoms, and the total number of injections required to achieve a therapeutic effect. Consequently, patient compliance is a significant issue.

We believe that a significant market opportunity exists for TOLAMBA in the treatment of moderate and severe ragweed allergic individuals currently using multiple prescription or OTC medications or undergoing conventional immunotherapy. In addition, the convenience of the six-week regimen and the unique, disease-modifying aspect of this technology present an opportunity to widen usage to a broader patient population.

### **Peanut and Cat Allergy Therapies**

Peanut allergy accounts for the majority of severe food-related allergic reactions. There are no currently available treatments. Cat allergy is one of the most common indoor allergens and a common cause of allergic asthma exacerbations. Current treatment is focused mainly on short-term, symptomatic treatments which offer limited efficacy for patients.

We believe that ISS linked to the major peanut and cat allergens may be able to suppress the Th2 response and reduce or eliminate the allergic reaction without inducing anaphylaxis during the course of therapy. Our anticipated advantage in this area is the potentially increased safety that may be achieved by linking ISS to the allergen. By using

ISS to block recognition of the allergen by IgE and therefore prevent subsequent histamine release, we may be able to administer enough of the ISS-linked allergen to safely reprogram the immune response without inducing a dangerous allergic reaction. We believe the resulting creation of memory Th1 cells may provide long-term protection against an allergic response.

## **Table of Contents**

### ***Preclinical Status***

*Peanut Allergy Therapy:* We have developed an initial peanut allergy product candidate that consists of ISS linked to a major peanut allergen. We have demonstrated in mice that peanut allergen linked to ISS induces much higher levels of Th1-induced IgG antibodies and lower levels of IgE than natural peanut allergen. Immunization with our product candidate has been shown to protect peanut allergic animals from anaphylaxis and death following exposure to peanut allergen. In addition, we have demonstrated that ISS-linked peanut allergen has significantly reduced allergic response as measured by in vitro histamine release assays using blood cells from peanut allergic patients.

*Cat Allergy Therapy:* We are currently producing a recombinant Fel d 1 protein, the dominant allergen in cat dander. This protein will then be conjugated to ISS and tested in preclinical models for reduced allergenicity, the ability to induce Th1 rather than Th2 responses, and the ability to reduce the symptoms of allergy to Fel d 1.

### ***Commercial Opportunity***

*Peanut Allergy Therapy:* Approximately 1.5 million people in the U.S. have a potentially life-threatening allergy to peanuts and the incidence is growing rapidly. There are an estimated 100 to 200 deaths from severe peanut allergy in the U.S. each year. Because there are currently no products available that treat peanut allergy, people allergic to peanuts must take extreme avoidance measures, carefully monitoring their exposure to peanuts and peanut by-products. Emergency response following peanut exposure and the onset of allergic symptoms primarily consists of the administration of epinephrine to treat anaphylaxis. Our peanut allergy therapy is designed to allow patients to tolerate exposure to higher levels of peanut products without experiencing severe reactions.

*Cat Allergy Therapy:* Cat allergy affects approximately 40% of the allergic rhinitis population in the U.S. and is unique in that patients are often highly motivated to seek therapeutic solutions due to significant quality of life impacts. Current treatment is focused mainly on short-term, symptomatic treatments which offer limited efficacy for patients, with immunotherapy requiring 60-90 injections over 3-5 years, leading to poor compliance and compromised efficacy. A disease-modifying treatment for cat allergy would meet a unique unmet medical need.

## **Influenza Vaccine**

Human viral influenza is an acute respiratory disease of global dimension with high morbidity and mortality in annual epidemics. In the U.S., there are an estimated 30 to 40 thousand viral flu-associated deaths per year. Pandemics occur infrequently, on average every 30 to 40 years, with high rates of infection resulting in increased mortality. The last pandemic occurred in 1968, and virologists anticipate that a new pandemic strain could emerge any time. Current flu vaccines are directed against specific surface antigen proteins. These proteins vary significantly each year, requiring the vaccine to be reformulated and administered annually. Our approach links advanced ISS to conserved flu antigens thereby generating potent antigens that confer immunity against divergent influenza strains. We believe that ISS-linked conserved antigens added to conventional vaccine will not only confer protective immunity against divergent flu strains but will also increase antibody responses to the conventional vaccine due to the potent adjuvant effect of the ISS component.

### ***Preclinical Status***

In the fourth quarter of 2006, we announced preclinical data that show our flu vaccine can improve the immunogenicity of conventional flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with conventional vaccine enhances the immune response of the vaccine, allows reduction of vaccine dosage, and provides extra layers of protection that are not strain-dependent. In August 2007, we were awarded a two-year \$3.25 million grant from the National Institute of Allergy and Infectious Diseases (NIAID),

a division of the National Institutes of Health (NIH), to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Our research focuses on incorporating a second-generation TLR9 agonist and the conserved influenza antigens

## **Table of Contents**

nucleoprotein (NP) and the extracellular domain of matrix protein 2 (M2e). The new grant is directed toward advancing preclinical research into IND-enabling studies and product development.

### ***Commercial Opportunity***

There are over 100M doses of influenza vaccines sold in the US alone every year, generating over \$1 billion in sales. The market continues to grow, as immunization rates increase and vaccine is readily available. The Dynavax approach is synergistic with both currently-marketed and development-stage influenza vaccines, including those targeting H5 virus, and has the potential to provide significant near and long-term competitive advantages by providing a highly differentiated vaccine for seasonal influenza and an optimal strategy for developing a vaccine effective against pandemic influenza caused by antigenic shift.

### **Additional Programs**

In addition to our primary development programs, our pipeline includes programs in Cancer, Hepatitis B Therapy, Asthma and Autoimmune Disorders.

### **Cancer Therapy**

In oncology, we believe that the potent and multifaceted biological activities of ISS offer a number of distinct approaches to cancer therapy in a wide range of tumor types. Extensive study in preclinical model systems has shown positive indications that ISS may offer several benefits. ISS can be used in different ways depending on patient/tumor profiles, either as monotherapy or in combination with chemotherapy and/or monoclonal antibodies. ISS may also have the potential be used to treat the full spectrum of solid tumors and hematologic malignancies due to the central role of TLR9 in immune regulation. ISS also has an attractive safety profile and is expected to offer fewer side effects as compared to currently available cancer therapies, increasing the likelihood of broad use.

In December 2006, we initiated a Phase 1 dose escalation clinical trial of our first generation cancer product candidate in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. In addition, a Phase 2 study has been completed in non-Hodgkin's lymphoma (NHL) of ISS in combination with Rituxa<sup>®</sup> (rituximab). In December 2006, we announced preliminary data from this Phase 2 study based on 23 patients with histologically confirmed CD20+, B-cell follicular NHL who had relapsed after at least one prior treatment regimen for lymphoma. This study showed a possible correlation between biomarker response to ISS and clinical outcomes; patients with high biomarker induction had a doubling of response rate and progression free survival versus patients with low biomarker induction. The combination of rituximab and our ISS was well-tolerated, and adverse events were minimal. We previously reported a Phase 1, dose-escalation trial of our ISS in combination with rituximab in 20 patients with NHL in which dose-dependent pharmacological activity was demonstrated without significant toxicity.

We are also pursuing the development of a second generation ISS product candidate offering enhanced potency that could potentially be used for cancer and hepatitis C therapy.

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 \$50.0 million in SDI to fund the Development Programs, and we licensed to SDI our intellectual property rights related to the Development Programs.

### **Hepatitis B Therapy**

Hepatitis B infection is a major cause of acute and chronic viral hepatitis, with morbidities ranging from asymptomatic infection to liver failure, cancer and death. Currently available therapies for chronic hepatitis B infection include interferon alpha and antiviral drugs. We are developing a potentially novel therapy to treat chronic hepatitis B infection that combines hepatitis B surface antigen and hepatitis B core antigen. Our

## **Table of Contents**

hepatitis B therapeutic candidate may provide a more effective alternative for the elimination of infection in chronic carriers, in conjunction with existing antiviral therapies. Our immunotherapy is expected to induce a potent immune response against virus-infected cells in the liver and has the potential to eradicate the infection. In March 2007, we initiated a Phase 1 study of this therapy in 20 healthy subjects, to evaluate the safety of the therapy at two dosing schedules.

### **Asthma**

In most people, asthma is an inflammatory airway disease caused by multiple allergens. As a result, an approach relying on the linkage of ISS to a large number of allergens would be technically and commercially challenging. To address this issue, we have formulated ISS for pulmonary delivery with no linked allergen, relying on natural exposure to multiple allergens that may produce specific long-term immunity. Once the immune response to asthma-causing allergens has been reprogrammed to a Th1 response, it may be possible to reduce administrations of ISS to longer periodic intervals or only as needed. In addition, based on preclinical data, we believe that this therapy may lead to reversal of airway remodeling caused by asthma.

In September 2006, we entered into a 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, or COPD. 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.

### ***Autoimmune Disorders***

We have pioneered a new approach to treating autoimmune disease based upon a class of oligonucleotides, named immunoregulatory sequences (IRS), that specifically inhibit the TLR-induced inflammatory response implicated in disease progression. We are exploring development of an IRS-based treatment for autoimmune diseases, including systemic lupus erythematosus (SLE or lupus).

### **Intellectual Property**

Our intellectual property portfolio can be divided into our main technology areas: ISS, vaccines using DNA and IRS. We have entered into exclusive, worldwide license agreements with the Regents of the University of California for technology and related patent rights in these technology areas.

*ISS technology:* We have 83 issued U.S. and foreign patents, 33 pending U.S. patent applications, and 92 pending foreign applications that seek worldwide coverage of compositions and methods using ISS technology. Some of these patents and applications have been exclusively licensed worldwide from the Regents of the University of California. Among others, we hold issued U.S. patents covering 1018 ISS as a composition of matter; the use of ISS alone to treat asthma; and ISS linked to allergens and viral or tumor antigens.

*Vaccines using DNA:* We have 27 issued U.S. and foreign patents and 5 pending U.S. and foreign patent applications covering methods and compositions for vaccines using DNA and methods for their use. We hold an exclusive, worldwide license from the Regents of the University of California for patents and patent applications relating to vaccines using DNA, and we have the right to grant sublicenses to third parties. Effective January 1998, we entered into a cross-licensing agreement with Vical, Inc. that grants each company exclusive, worldwide rights to combine the other firm's patented technology for DNA immunization with its



own for selected indications.

*IRS including immunoinhibitory sequences:* We have 2 issued U.S. and foreign patents and 19 pending U.S. and foreign patent applications to certain compositions and methods using IRS (including immunoinhibitory sequences). Some of these patents and patent applications have been exclusively licensed worldwide from the Regents of the University of California.

## **Table of Contents**

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.

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., or Pfizer, as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover technologies similar to the technologies 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. 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. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors. 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. We have developed second-generation technology that we believe reduces many of these risks.

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. U.S. Patent Office interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. 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. We may not prevail in any of these actions or proceedings 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.

Our policy is to require each of our 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.

## **Manufacturing**

We rely on a number of third parties and our facility in Düsseldorf, Germany 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 combination of the antigens and ISS, and the fill and finish.

The process for manufacturing oligonucleotides such as ISS is well established and uses commercially available equipment and raw materials. To date, we have manufactured small quantities of our oligonucleotide formulations for research purposes. We have relied on a single supplier to produce our ISS for clinical trials.

HEPLISAV is composed of hepatitis B surface antigen combined with 1018 ISS. We currently utilize our facility in Düsseldorf, Germany to manufacture Hepatitis B surface antigen. In October 2007, we entered into a global license

and development collaboration agreement with Merck to jointly develop HEPLISAV. Under the terms of the agreement, we are responsible for manufacturing the hepatitis B surface antigen component of the vaccine for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility

## **Table of Contents**

using our proprietary technology developed there and later, at our expanded facility to support expected market needs.

TOLAMBA consists of ISS linked to Amb a 1, the principal ragweed allergen, which is purified from ragweed pollen purchased on an as-needed basis from commercial suppliers of ragweed pollen. If we are unable to purchase ragweed pollen from commercial suppliers, we may be required to contract directly with collectors of ragweed pollen which may in turn subject us to unknown pricing and supply risks. As we develop product candidates addressing other allergies, we may face similar supply risks. In the past, TOLAMBA was produced for us by a single contract manufacturer. Our existing supplies of TOLAMBA are sufficient for us to conduct our current clinical trials. We may enter into manufacturing agreements with one or more new commercial manufacturers to produce additional supplies of TOLAMBA if required to advance the program toward commercialization.

## **Marketing**

We have no sales, marketing or distribution capability. We intend to seek global or regional partners to help us market certain product candidates. We are inclined to license commercial rights to larger pharmaceutical or biotechnology companies with appropriate marketing and distribution capabilities, except in instances where it may prove feasible to build a small direct sales organization targeting a narrow specialty or therapeutic area.

## **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, if approved and commercialized, will compete directly with existing, three-dose vaccine products produced by GlaxoSmithKline plc (GSK) and Crucell N.V., among others. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in European Union and United States. In addition, HEPLISAV will compete against a number of multivalent vaccines that simultaneously protect against hepatitis B in addition to other diseases.

TOLAMBA, if approved and commercialized, will compete directly with conventional allergy immunotherapy. Conventional allergy immunotherapy products are mixed by allergists and customized for individual patients from commercially available plant material extracts. Because conventional immunotherapies are customized on an individual patient basis, they are not marketed or sold as FDA approved pharmaceutical products. Other companies such as ALK-Abello/Schering-Plough Corporation, Allergy Therapeutics plc, and Cytos Biotechnology are developing enhanced allergy immunotherapeutic products formulated for injection, oral and sublingual delivery. A number of companies, including GSK, Merck, and AstraZeneca, produce pharmaceutical products, such as antihistamines, corticosteroids and anti-leukotriene agents, which manage allergy symptoms. We consider these pharmaceutical products to be indirect competition for TOLAMBA because although they are targeting the same disease, they do not attempt to treat the underlying cause of the disease.

Our universal influenza vaccine, if approved and commercialized, will compete with traditional and emerging influenza vaccines from companies currently marketing these products, including GSK, Novartis, Sanofi-Pasteur, Medimmune/AstraZeneca and CSL. In addition, we are aware of several companies developing potentially competing universal vaccines for influenza, including Acambis, VaxInnate, Merck and Vical.

Our TLR9 agonist therapy for cancer, if approved and commercialized, will compete directly with other TLR9 agonist therapies such as those in development by Pfizer, Inc. and Idera Pharmaceuticals, Inc. In addition, our cancer therapy may compete directly or indirectly with cytotoxic therapies and biologics in development from other parties, including but not limited to Amgen, Bristol-Myers Squibb, Genentech,

## **Table of Contents**

Schering-Plough Corporation, and Pfizer, Inc. Standards of care can evolve rapidly in oncology and our ability to develop our therapies to be compatible with evolving standards of care will be critical.

Our hepatitis B therapy, if developed, approved and commercialized, may compete directly with existing hepatitis B therapeutic products (including antiviral drugs and interferon alpha) manufactured by Roche Group, Schering-Plough Corporation, Gilead Sciences, Inc., GSK and other companies.

Our ISS asthma product candidate would indirectly compete with existing asthma therapies, including corticosteroids, leukotriene inhibitors and IgE monoclonal antibodies, including those produced by Novartis, AstraZeneca, Schering-Plough Corporation and GSK. We consider these existing therapies to be indirect competition because they only attempt to address the symptoms of the disease and, unlike our product candidate, do not attempt to address the underlying cause of the disease. We are also aware of a preclinical inhaled product, which may target the underlying cause of asthma, rather than just the symptoms, which is being developed by Sanofi-Aventis under a collaboration agreement with Pfizer. This product, if approved and commercialized, may compete directly with our asthma 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 us. Smaller or early-stage companies may also prove to be significant competitors, particularly for collaborative agreements with large, established companies and access to capital. These entities may also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs.

## **Regulatory Considerations**

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

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

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

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

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

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

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

To secure FDA approval, we must submit extensive non-clinical and clinical data, manufacturing information, and other supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. The number of preclinical studies and clinical trials that will be required for FDA and foreign regulatory agency approvals varies depending on the product candidate, the disease or condition for which the product candidate is in development and regulations applicable to any particular drug candidate.

**Table of Contents**

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.

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

## **Table of Contents**

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.

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, 2007, we had 173 full-time employees, including 26 Ph.D.s, 3 M.D.s and 23 others with advanced degrees. Of the 173 employees, 131 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement, and we believe our relations with our employees are good.

## **Available Information and Website Address**

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

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

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

**Table of Contents**

*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 \$227.9 million as of December 31, 2007. 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 and are scheduled to terminate in 2009. We anticipate that we will incur substantial additional net losses for the foreseeable future as a result of our investment in research and development activities.

We do not have any products that generate significant revenue. Clinical trials for certain of our 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 or raise additional capital on less favorable terms.

**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 may not allow us to continue operations as currently planned. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations, and any change in plans may increase these outlays and expenditures. 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 TLR9 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 TLR9 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 TLR9 product candidates. 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, we recently announced a clinical hold by the FDA on two Investigational New Drug (IND) applications for HEPLISAV due to a serious adverse event (SAE) in a Phase 3 study. Pending further investigation and resolution satisfactory to the FDA and foreign regulatory authorities, there can be no assurance that HEPLISAV can be further developed, or even

## **Table of Contents**

if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies or patient data.

Many new drug candidates, including many drug candidates that have completed Phase 3 clinical trials, have shown promising results in early clinical trials and subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations.

**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. In addition, our ability to conduct clinical trials for some of our product candidates is limited due to the seasonal nature. 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 an entire year.

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;
- 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

**Table of Contents**

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 candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, 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 candidates in clinical trials are based on our 1018 ISS compound, and substantially all 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. In addition, as all 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 and for fulfilling our manufacturing obligations under our collaboration with Merck. 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 or breach of our obligations under our Merck collaboration.**

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 combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

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

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

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV, which is part of our collaboration with Merck & Co., Inc, or Merck. We are obligated to manufacture, on behalf of Merck, HEPLISAV for clinical development and commercial quantities of hepatitis B surface antigen until such time as we can effect the appropriate technology transfer to Merck. Accordingly, we will have to allocate the entire capacity of our Düsseldorf facility to meet our obligations under the Merck collaboration. Moreover, in order to meet our commercial supply obligations to Merck, we expect to have to establish commercial-scale manufacturing capability for HEPLISAV, which will involve increased capital and operating costs and the assumption of risks associated with the construction, validation and operation of a new commercial manufacturing facility as well as the continued operation of our existing facility. There can be no assurance that we can successfully meet our supply obligations to



Merck and maintain our internal product candidate timelines and, if we undertake the establishment of a new commercial manufacturing facility, that we can finance the capital costs and ongoing expenses that we would need to undertake until or if HEPLISAV

**Table of Contents**

achieves commercial success. There also can be no assurance that the cost of meeting our supply obligation to Merck will be covered by the negotiated supply price.

**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 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, 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.

In October 2007, we entered into a collaborative arrangement with Merck in which we and Merck will further develop and commercialize HEPLISAV. Pursuant to the terms of the collaboration, we are obligated to complete ongoing clinical studies, manufacture and supply on behalf of Merck, and conduct technology transfer with respect to our existing HEPLISAV development program. Although we will be reimbursed for specified development efforts and the delivery of clinical material to Merck in the further development and commercialization of HEPLISAV, Merck controls the development and commercialization plans and timelines for the product. We recently announced that two IND applications for HEPLISAV have been placed on clinical hold by the FDA due to a SAE. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development. Merck may terminate the arrangement upon written notice to us, and there can be no assurance that Merck will continue the collaboration

regardless of whether or not the clinical hold by the FDA is released. Moreover, even if the collaboration continues, we may not successfully and timely fulfill our obligations under the collaboration, Merck may develop or market a potentially competitive product, or HEPLISAV, even if successfully developed, may not achieve commercial success sufficient for us to achieve all of the milestones and royalties contemplated under the collaborative arrangement.

**Table of Contents**

**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;

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

adverse tax consequences;

**Table of Contents**

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 might 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
- 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.

**Our TLR9 allergy program, including the development of TOLAMBA, relies on debt funding that is accessible only on the achievement of specified development milestones. We may not be able to achieve the milestones in a timely manner and as a result may not receive or have access to sufficient funding to continue further development of TOLAMBA. Even if we achieve such milestones, we will be obligated to**

**Table of Contents**

**repay up to \$30 million in July 2010 and we may not have sufficient funds to pay such amounts upon maturity.**

In July 2007, we entered into a funding arrangement with Deerfield management, or Deerfield, to support our further development of our allergy product programs, including TOLAMBA. Our continued access to the funding is dependent upon our successful achievement of specified milestones in a timely manner. There can be no assurance that TOLAMBA will be entered into planned clinical studies or successfully achieve the planned end points, and failure to successfully further develop TOLAMBA according to our current clinical plans may result in the termination of further development efforts. Moreover, even if we achieve the planned clinical results, we will be required to issue additional warrants to purchase up to 2,000,000 shares of our Common Stock and repay outstanding loans to the Deerfield. 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 repay the loan at maturity. 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 have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some or all of the programs in the future. 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 therapeutics (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 \$50.0 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 \$74.7 to \$144.1 million. 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 \$15.0 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 substantial payment of at least \$74.7 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.

## **Table of Contents**

### **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.

### **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;

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

**Table of Contents**

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;

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; and

volume of trading in our common stock

One or more of these factors could cause a decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially 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.

**Anti-takeover provisions of our certificate of incorporation, bylaws and Delaware law 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.

In addition, we are 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 five 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 we grow our business and organization 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 as we grow 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 control 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 September 2009 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 Global 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 on the Nasdaq Global Market.

	Common Stock Price	
	High	Low
<b>2007</b>		
First Quarter	\$ 9.24	\$ 4.56
Second Quarter	\$ 5.81	\$ 3.98
Third Quarter	\$ 5.19	\$ 3.60
Fourth Quarter	\$ 5.80	\$ 4.17
<b>2006</b>		
First Quarter	\$ 6.60	\$ 4.07
Second Quarter	\$ 6.20	\$ 4.12
Third Quarter	\$ 4.69	\$ 3.62
Fourth Quarter	\$ 10.66	\$ 4.21

As of February 29, 2008, 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 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates. We anticipate filing the related prospectus supplement by April 2008.

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 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.

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

**Table of Contents**

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.

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, 2007, 2006 and 2005 and the Consolidated Balance Sheets Data as of December 31, 2007 and 2006 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, 2004 and 2003 and the Consolidated Balance Sheets Data as of December 31, 2005, 2004 and 2003 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.

	<b>Years Ended December 31,</b>				
	<b>2007(1)</b>	<b>2006(1)</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except per share data)</b>				
<b>Consolidated Statements of Operations</b>					
<b>Data:</b>					
Total revenues	\$ 14,093	\$ 4,847	\$ 14,655	\$ 14,812	\$ 826
Operating expenses:					
Research and development(3)	65,888	50,116	27,887	23,129	13,786
General and administrative	18,293	14,836	9,258	8,543	4,804
Acquired in-process research and development(2)		4,180			
Amortization of intangible assets	1,004	698			
Total operating expenses	85,185	69,830	37,145	31,672	18,590
Loss from operations	(71,092)	(64,983)	(22,490)	(16,860)	(17,764)
Interest and other income, net	4,165	3,287	2,125	919	412
Interest expense	(1,719)	(99)	(190)	(30)	
Deemed dividend					(633)
Loss including noncontrolling interest in Symphony Dynamo, Inc.	\$ (68,646)	\$ (61,795)	\$ (20,555)	\$ (15,971)	\$ (17,985)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	8,675	9,743			
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)	\$ (15,971)	\$ (17,985)
Basic and diluted net loss per share	\$ (1.51)	\$ (1.61)	\$ (0.79)	\$ (0.75)	\$ (10.04)
Shares used in computing basic and diluted net loss per share	39,746	32,339	25,914	21,187	1,791

- (1) Our net loss for the years ended December 31, 2007 and December 31, 2006 includes approximately \$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) 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.
- (3) 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.

**Table of Contents**

	2007	2006	December 31, 2005 (In thousands)	2004	2003
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and marketable securities	\$ 56,617	\$ 72,831	\$ 75,110	\$ 65,844	\$ 29,097
Investments held by Symphony					
Dynamo, Inc.	31,631	13,363			
Working capital	82,035	75,985	71,941	64,017	26,340
Total assets	120,449	102,890	80,093	73,646	31,585
Noncontrolling interest in Symphony					
Dynamo, Inc.	8,341	2,016			
Minority interest in Dynavax Asia					14,733
Convertible preferred stock					83,635
Accumulated deficit	(227,914)	(167,943)	(115,891)	(95,336)	(79,365)
Total stockholders' equity (net capital deficiency)	30,790	77,056	74,363	59,876	(71,932)

**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 is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent infectious diseases, allergies, cancer and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

Our product candidates include: HEPLISAV™, a hepatitis B vaccine in Phase 3 partnered with Merck & Co., Inc.; TOLAMBA™, a ragweed allergy therapy in Phase 2; a therapy for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca AB. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer and hepatitis C therapeutic programs. Deerfield Management, a healthcare investment fund, and its affiliates (Deerfield), have committed funding

for our allergy programs.

## **Recent Developments**

### ***HEPLISAV***

HEPLISAV, our product candidate for hepatitis B prophylaxis, is based on proprietary ISS that specifically targets TLR9 to stimulate an innate immune response. HEPLISAV combines ISS with hepatitis B

## **Table of Contents**

surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection. Previously reported clinical trial results have shown 100% seroprotection after two doses in subjects 18 to 39 years of age, and after three doses in difficult-to-immunize subjects 40 to 70 years of age.

We recently announced that two Investigational New Drug (IND) applications for HEPLISAV have been placed on clinical hold by the U.S. Food and Drug Administration (FDA) due to a serious adverse event (SAE) that occurred in one subject who received HEPLISAV in a Phase 3 study being conducted outside the United States. The subject was preliminarily diagnosed to have Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed. All subjects in this Phase 3 clinical study have received all doses per the study protocol, and will continue to be monitored. Administration of vaccine has been suspended in the only study of HEPLISAV where injections were being administered actively, a fully enrolled Phase 2 study in End Stage Renal Disease (ESRD) subjects being conducted in Canada. A total of approximately 2,500 individuals have been vaccinated with more than 5,000 doses of HEPLISAV in 10 clinical trials spanning approximately seven years. No additional HEPLISAV clinical trials will be initiated until the clinical hold has been resolved. We and Merck & Co., Inc. (Merck), along with additional collaborators, including clinical investigators and leading experts, are investigating the medical history of the individual who experienced the SAE to understand better the onset of this diagnosed disease, including whether it was a pre-existing condition. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development, or that if HEPLISAV continues in development, that the FDA will not require significant limitations impacting the timing and clinical data required to achieve approval.

In October 2007, we entered into a global license and development collaboration agreement with Merck to jointly develop HEPLISAV. 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 an initial upfront payment of \$31.5 million, and will be eligible to receive development cost reimbursement, future development and sales milestone payments up to \$105 million, and double-digit tiered royalties on global sales of HEPLISAV. Under Merck's supervision, we continue to manage the ongoing Phase 3 study in Canada and Europe as well as other licensure-required studies. The United States Food and Drug Administration Biologics Licensing Application (BLA) and other marketing applications will be the joint responsibility of Merck and Dynavax, and are intended to be submitted by Merck. Also in October 2007, we entered into a manufacturing agreement with Merck. We are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility using our proprietary technology developed there and later, at our expanded facility to support expected market demand. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV. As a result of the clinical hold, there can be no assurance that HEPLISAV can continue in further development. Merck may terminate the agreement upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA is released.

## **Allergy Franchise**

### ***TOLAMBA***

TOLAMBA, our product candidate for the treatment of ragweed allergy, consists of ISS linked to the purified major allergen of ragweed, Amb a 1. TOLAMBA is designed to target the underlying cause of seasonal allergic rhinitis caused by ragweed. The linking of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy.

In October 2007, we began dosing of TOLAMBA in subjects as part of an environmental exposure chamber study. Subjects were screened based on a history of ragweed allergy and a positive skin test. Exposure to ragweed allergen in



the chamber is being used to select those individuals with confirmed ragweed allergic disease and establish their baseline level of symptoms. Subjects are being treated and will be re-exposed in the chamber to determine the effect of the six-week, six-injection TOLAMBA regimen as

## **Table of Contents**

compared to placebo. Data from this study are expected in the first half of 2008 and, if positive, we intend to initiate a pivotal field study to support a potential BLA submission.

### ***Peanut and Cat Allergy Therapies***

Our peanut and cat allergy programs involve direct linkage of certain allergens to a proprietary TLR9 agonist. This approach is designed to mask the IgE binding sites of the native allergen to ensure safety and to induce an allergen-specific Th1 to Th2 immune shift to reprogram the immune response in allergic patients. Preclinical proof of concept studies have been generated with our peanut allergy approach, which provided protection in a mouse model of peanut induced anaphylaxis. We anticipate that the clinical development path for a disease-modifying peanut and cat allergy therapies to be focused on established challenge studies, in which both patient selection and study timing can be tightly controlled.

In July 2007, Deerfield committed up to \$30 million in project financing for a chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs.

### ***Influenza Vaccine***

We are developing a universal flu vaccine designed specifically to overcome the limitations of standard seasonal and pandemic vaccines. Our approach combines standard flu vaccine, required for generating neutralizing antibodies against matched strains, with conserved antigens (NP and M2e) conjugated to a proprietary ISS. The ISS component enhances the immune response to standard vaccine, potentially increasing the efficacy and reducing the amount of antigen required. The conserved antigens enable protection against mismatched and pandemic strains, regardless of which strain ultimately causes a pandemic. This is a key differentiator versus other pandemic vaccines, most of which specifically target an individual H5 or H9 strain that may not ultimately acquire the characteristics of a potentially pandemic strain.

In August 2007, we were awarded a two-year \$3.25 million grant from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), to continue development of our universal influenza vaccine. The new grant is directed toward advancing preclinical research into IND-enabling studies and product development.

## **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 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

## **Table of Contents**

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.

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 are expensed upon the earlier of when non-refundable amounts are due or as services are 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 will be 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 will require 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 will be expensed as the related goods are delivered or services are performed. We do not expect this pronouncement to have a material effect on our consolidated financial statement.

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

## **Table of Contents**

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.

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.

As a result of the adoption of FAS 123R, we reduced our deferred stock compensation balance and additional paid in capital by \$2.5 million as of January 1, 2006. As of December 31, 2007, the total unrecognized compensation cost related to unvested options granted amounted to \$6.8 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.6 years.

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 11%, 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 employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 5 years. Non-executive level employees were found to have historical option exercise and termination behavior that resulted in an expected life of 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. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

**Table of Contents**

***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 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; 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);

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

**Table of Contents**

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.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, which Holdings distributed to Symphony. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model. In consideration for the warrant, 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 that range from \$74.7 million at the end of the second year of the arrangement, increasing quarterly up to \$144.1 million at the fifth anniversary. 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 \$15.0 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.

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 Vice President of Clinical Development 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

## **Table of Contents**

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.

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, 2007, the noncontrolling interest balance was \$8.3 million, which we currently expect to be exhausted by the end of 2008. As of December 31, 2007, the investments held by SDI were \$31.6 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, 2007. 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.

**Table of Contents**

The following is a summary of our revenues for the years ended December 31, 2007, 2006 and 2005 (in thousands, except for percentages):

Revenues:	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
Collaboration revenue	\$ 9,315	\$ 1,557	\$ 12,199	\$ 7,758	498%	\$ (10,642)	(87)%
Grant revenue	3,046	1,549	2,456	1,497	97%	(907)	(37)%
Services and license revenue	1,732	1,741		(9)	(1)%	1,741	
Total revenues	\$ 14,093	\$ 4,847	\$ 14,655	\$ 9,246	191%	\$ (9,808)	(67)%

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 arrangements 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 National Institutes of Health (NIH) awards, following the resolution of a vendor restriction. In addition, the Company was awarded a two-year \$3.25 million grant in August 2007 from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the NIH, to continue development of a novel universal influenza vaccine. The Company recognized approximately \$0.5 million for the year ended December 31, 2007 relating to this grant. Services and license revenue of \$1.7 million was derived primarily from R&D services provided to customers of Dynavax Europe.

Collaboration revenue for the year ended December 31, 2006 decreased by \$10.6 million, or 87%, over the same period in 2005. Collaboration revenue for the year ended December 31, 2005 included an acceleration of revenue recognition of \$7.0 million resulting from the termination of our collaboration with UCB in March 2005. Grant revenue for the year ended December 31, 2006 decreased by \$0.9 million, or 37%. Grant revenue for the year ended December 31, 2005 included \$0.5 million associated with an adjustment to the final approved indirect cost rate utilized for our NIH awards.

We anticipate that our revenues will increase significantly in 2008 as compared to 2007 due primarily to our collaboration with Merck. Depending upon the resolution of the HEPLISAV clinical hold by the FDA, there could be an impact on the timing of the Merck-related revenues, including the recognition of the upfront payment and future development cost reimbursement.

**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; impairment and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing our product candidates. We expense our research and development costs as they are incurred.

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

**Increase                      Increase**

<b>Research and Development:</b>	<b>Years Ended December 31,</b>			<b>(Decrease) from</b>		<b>(Decrease) from</b>	
	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2006 to 2007</b>	<b>2006 to 2007</b>	<b>2005 to 2006</b>	<b>2005 to 2006</b>
				<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Compensation and related personnel costs	\$ 19,170	\$ 13,006	\$ 8,563	\$ 6,164	47%	\$ 4,443	52%
Outside services	38,726	31,042	15,084	7,684	25%	15,958	106%
Facility costs	6,414	4,988	3,673	1,426	29%	1,315	36%
Impairment	444			444	100%		
Non-cash stock-based compensation	1,134	1,080	567	54	5%	513	90%
Total research and development	\$ 65,888	\$ 50,116	\$ 27,887	\$ 15,772	31%	\$ 22,229	80%

**Table of Contents**

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 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 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.

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.

Research and development expenses for the year ended December 31, 2006 increased by \$22.2 million, or 80%, from the same period in 2005. The increase from fiscal year 2005 was primarily due to increased clinical trial and clinical material manufacturing costs for our product candidates TOLAMBA and HEPLISAV, as well as expenses incurred to support the SDI programs and Dynavax Europe operations. Outside services during the period also included approximately \$0.1 million of costs associated with the manufacture of Supervax formulated bulk vaccine. Compensation and related personnel costs increased in 2006 due to continued organizational growth to further develop our clinical candidates and the acquisition of Dynavax Europe. Facility costs increased primarily due to rent expense for Dynavax Europe. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

We anticipate that our research and development expenses will increase significantly in 2008 as compared to 2007, primarily in connection with the advancement of HEPLISAV, TOLAMBA and other programs.

***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, net of patent cost recoveries; allocated facility costs; and

**Table of Contents**

non-cash stock-based compensation. The following is a summary of our general and administrative expense (in thousands, except for percentages):

<b>General and Administrative:</b>	<b>Years Ended December 31,</b>			<b>Increase (Decrease) from</b>		<b>Increase (Decrease) from</b>	
	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2006 to 2007</b>		<b>2005 to 2006</b>	
				<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Compensation and related personnel costs	\$ 7,101	\$ 6,264	\$ 4,426	\$ 837	13%	\$ 1,838	42%
Outside services	5,248	4,008	2,372	1,240	31%	1,636	69%
Legal costs	2,951	1,727	1,117	1,224	71%	610	55%
Facility costs	610	591	510	19	3%	81	16%
Other		43		(43)	(100)%	43	
Non-cash stock-based compensation	2,383	2,203	833	180	8%	1,370	164%
<b>Total general and administrative</b>	<b>\$ 18,293</b>	<b>\$ 14,836</b>	<b>\$ 9,258</b>	<b>\$ 3,457</b>	<b>23%</b>	<b>\$ 5,578</b>	<b>60%</b>

General and administrative expenses for the year ended December 31, 2007 increased by \$3.5 million, or 23%, over 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 development activities, SDI programs and Dynavax Europe operations.

General and administrative expenses for the year ended December 31, 2006 increased by \$5.6 million, or 60%, over the same period in 2005. The increase from fiscal 2005 primarily reflects additional compensation and related personnel costs associated with overall organizational growth, including the impact of Dynavax Europe. Outside services and legal costs increased in 2006 related to higher accounting fees, consulting fees incurred in conjunction with various corporate development activities, and expenses incurred to support SDI programs and Dynavax Europe operations. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

We expect general and administrative expenses to increase modestly in 2008 as compared to 2007, resulting from continued organizational growth and expenses incurred to support corporate development activities.

***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 have 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):



<b>Program</b>	<b>Description</b>	<b>Estimated Acquisition Date Fair Value</b>
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 therapeutic 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

## **Table of Contents**

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 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.

We intend to continue further development of a therapy to treat chronic hepatitis B infection. In March 2007, we initiated a Phase 1 clinical study of our hepatitis B therapeutic candidate in 20 healthy subjects. 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.

### ***Amortization of Intangible Assets***

Intangible assets consist primarily of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was \$1.0 million for the year ended December 31, 2007 compared to \$0.7 million for the same period in 2006.

### ***Interest and Other Income, Net and Interest Expense***

Interest income is reported net of amortization on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily

**Table of Contents**

with Dynavax Europe and gains and losses on disposals of property and equipment. The following is a summary of our interest and other income, net (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
Interest and other income, net	\$ 4,165	\$ 3,287	\$ 2,125	\$ 878	27%	\$ 1,162	55%
Interest expense	\$ (1,719)	\$ (99)	\$ (190)	\$ 1,620	1,636%	\$ (91)	(48%)

Interest and other income, net 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. 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. Interest and other income, net for the year ended December 31, 2006 increased by \$1.2 million, or 55%, over the same period in 2005. The increase was primarily caused by interest earned on the investments held by SDI of approximately \$0.5 million and the investment of proceeds from our financing activities in the fourth quarter of 2006.

***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 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, 2007 and 2006, the losses attributed to the noncontrolling interest were \$8.7 million and \$9.7 million, respectively.

**Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (Issue 07-3), 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. Issue 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 is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008. We do not expect this Issue to have a material effect on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), The Fair Value Option for Financial Assets and Financial Liabilities, which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss

from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 159 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

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

## **Table of Contents**

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 must adopt SFAS 157 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Financial Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48). We adopted the provisions of FIN 48 on January 1, 2007. 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, 2008.

## **Liquidity and Capital Resources**

As of December 31, 2007, we had \$56.7 million in cash, cash equivalents and marketable securities and \$31.6 million in investments held by SDI. Our funds are currently invested in a variety of securities, including highly liquid institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

We have financed our operations since inception primarily through the sale of shares of our common stock, shares of our convertible preferred stock, and ordinary shares in a subsidiary, which have yielded a total of approximately \$222 million in net cash proceeds. To a lesser extent, we have financed our operations through amounts received under collaborative agreements and government grants. We have also financed certain of our research and development activities under our agreements with SDI and Deerfield.

We completed an initial public offering in February 2004, raising net proceeds of approximately \$46.5 million from the sale of 6,900,000 shares of common stock. In the fourth quarter of 2005, we completed an underwritten public offering that resulted in net proceeds of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. In the fourth quarter of 2006, we completed a follow-on offering raising approximately \$29.3 million from the sale of 7,130,000 shares of common stock.

In August 2006 we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd. Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of \$30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the 18-month term of the purchase agreement. From time to time over the term of the purchase agreement, and at our sole discretion, we may present Azimuth with draw down notices constituting offers to purchase our common stock. The per share purchase price for these shares is at a discount ranging from 5.2% to 7.0%. In December 2006, we completed a draw down on our equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of our common stock. A total of \$15 million remains available on our equity line of credit through the extended term of the agreement, which is December 31, 2008.

In July 2007, Deerfield committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loan principal for TOLAMBA is contingent upon the positive outcome of

the chamber study and subsequent field study. If the TOLAMBA program is discontinued, we have no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive 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 average share price in the 15-day period prior to achievement of the milestone. If all milestones are successfully achieved, Deerfield would receive warrants for the purchase of up to a total of 5,550,000 shares of the

**Table of Contents**

Company's common stock during the term of the loan agreement. As of December 31, 2007, we issued 3,550,000 warrants to Deerfield, and \$5.5 million remained outstanding under the loan agreement.

In October 2007, we entered into a global license and development collaboration agreement with Merck to jointly develop HEPLISAV. 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 an initial upfront payment of \$31.5 million during the fourth quarter 2007, and will be eligible to receive development cost reimbursement, future development and sales milestone payments up to \$105 million, and double-digit tiered royalties on global sales of HEPLISAV.

Cash used in operating activities of \$32.0 million during the year ended December 31, 2007 compared to \$37.2 million for the same period in 2006. The decrease in cash usage over the prior year was due primarily to 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 used in operating activities during 2006 increased from 2005 primarily due to the increase in cash usage over the prior year was due primarily to the increase in our net loss from operations and the increase in working capital, offset by the receipt of \$10.0 million in upfront fees from our collaboration with AstraZeneca.

Cash used in investing activities of \$3.6 million during the year ended December 31, 2007 compared to \$20.4 million for the same period in 2006. The decrease was attributed to the net proceeds from maturities of marketable securities. Cash used in investing activities during 2006 increased from 2005 due to \$14.0 million in cash paid to acquire Rhein and \$13.4 million in purchases of investments held by SDI, net of proceeds from sales of marketable securities.

Cash provided by financing activities of \$35.7 million during the year ended December 31, 2007 compared to \$62.9 million for the same period in 2006. Cash provided by financing activities primarily included \$30 million in proceeds from the purchase of the noncontrolling interest in SDI and \$5.5 million in loan proceeds from Deerfield. Cash provided by financing activities during 2006 increased from 2005 primarily due to proceeds from equity offerings and \$17.4 million in proceeds from the purchase of the noncontrolling interest in SDI, net of fees.

We currently anticipate that our cash and marketable securities, collaboration agreements, investments held by SDI, available funds under our Azimuth equity line of credit, and Deerfield financing arrangement 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.

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 arrangements at an earlier stage of development on less favorable terms than we would otherwise choose.



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

The following summarizes our significant contractual obligations as of December 31, 2007 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More Than 5 Years</b>
Future minimum payments under our operating lease, excluding payments from the sublease agreement	\$ 22,596	\$ 2,073	\$ 7,780	\$ 5,548	\$ 7,195
Long-term liability from the program option exercised under the SDI collaboration	15,000			15,000	
Future commitment fees under our financing agreement with Deerfield	4,512	1,770	2,742		
Long-term liability from Deerfield financing agreement	5,500		5,500		
<b>Total</b>	<b>\$ 47,608</b>	<b>\$ 3,843</b>	<b>\$ 16,022</b>	<b>\$ 20,548</b>	<b>\$ 7,195</b>

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in September 2009 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 \$25 thousand through 2007 and \$55 thousand annually 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 subsequent exercise of the purchase option.

As of December 31, 2007, we have drawn down \$5.5 million from the Deerfield financing agreement in which the outstanding principal will be due in July 2010.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. 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.

In October 2007, we entered into a manufacturing agreement with Merck for the supply of hepatitis B surface antigen. Under the terms of the agreement, we are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility using our proprietary technology developed there and later, at our expanded facility to support expected market demand. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV.

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

## **Table of Contents**

development programs. Under the terms of the agreements, we may be required to pay future upfront 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, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 million through 2012. 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, 2007, such fees and milestone payments to the Regents could approximate \$1 million in 2008.

### ***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 maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity. 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, 2007 was \$0.3 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page No.</b>
<u>Report of Independent Registered Public Accounting Firm</u>	51
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	52
<u>Consolidated Statements of Operations</u>	53
<u>Consolidated Statements of Stockholders' Equity</u>	54
<u>Consolidated Statements of Cash Flows</u>	55
<u>Notes to Consolidated Financial Statements</u>	56

**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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, under the heading Stock-Based Compensation, in 2006 Dynavax Technologies Corporation changes its method of accounting for stock-based compensation.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2007, 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 13, 2008, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Francisco, California  
March 13, 2008

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,293	\$ 14,154
Marketable securities	42,324	58,677
Investments held by Symphony Dynamo, Inc. (SDI)	31,631	13,363
Restricted cash	408	408
Accounts receivable	7,234	2,154
Inventory		257
Prepaid expenses and other current assets	6,049	673
Total current assets	101,939	89,686
Property and equipment, net	7,314	5,200
Goodwill	2,312	2,312
Other intangible assets, net	3,239	4,382
Other assets	5,645	1,310
Total assets	\$ 120,449	\$ 102,890
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 4,418	\$ 2,181
Accrued liabilities	12,059	10,742
Deferred revenues	3,427	778
Total current liabilities	19,904	13,701
Deferred revenues, noncurrent	40,792	10,000
Liability from program option exercised under the SDI collaboration	15,000	
Other long-term liabilities	5,622	117
Noncontrolling interest in SDI	8,341	2,016
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, 2007 and 2006		
Common stock: \$0.001 par value; 100,000 shares authorized at December 31, 2007 and 2006; 39,765 and 39,715 shares issued and outstanding at December 31, 2007 and 2006, respectively	40	40
Additional paid-in capital	258,266	244,787
Accumulated other comprehensive income:		
Unrealized gain on marketable securities available-for-sale	138	28

Cumulative translation adjustment	260	144
Accumulated other comprehensive income	398	172
Accumulated deficit	(227,914)	(167,943)
Total stockholders' equity	30,790	77,056
Total liabilities, noncontrolling interest and stockholders' equity	\$ 120,449	\$ 102,890

*See accompanying notes.*

Table of Contents

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

(In thousands, except per share amounts)

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Revenues:			
Collaboration revenue	\$ 9,315	\$ 1,557	\$ 12,199
Grant revenue	3,046	1,549	2,456
Service and license revenue	1,732	1,741	
Total revenues	14,093	4,847	14,655
Operating expenses:			
Research and development	65,888	50,116	27,887
General and administrative	18,293	14,836	9,258
Acquired in-process research and development		4,180	
Amortization of intangible assets	1,004	698	
Total operating expenses	85,185	69,830	37,145
Loss from operations	(71,092)	(64,983)	(22,490)
Interest and other income, net	4,165	3,287	2,125
Interest expense	(1,719)	(99)	(190)
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(68,646)	(61,795)	(20,555)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	8,675	9,743	
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)
Basic and diluted net loss per share	\$ (1.51)	\$ (1.61)	\$ (0.79)
Shares used to compute basic and diluted net loss per share	39,746	32,339	25,914

*See accompanying notes.*



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

(In thousands, except share amounts)

	<b>Common Stock</b>	<b>Additional</b>	<b>Deferred</b>	<b>Notes</b>	<b>Other</b>	<b>Accumulated</b>	<b>Stockholders</b>	
	<b>Shares</b>	<b>Par Amount</b>	<b>Paid-In Capital</b>	<b>Stock Compensation</b>	<b>From Stockholders</b>	<b>Income (Loss)</b>	<b>Accumulated Deficit</b>	
							<b>Equity</b>	
Balances at December 31, 2004	24,627	\$ 25	\$ 159,074	\$ (3,366)	\$ (419)	\$ (102)	\$ (95,336)	\$ 59,876
Issuance of common stock upon public offering	5,720	5	33,132					33,137
Exercise of stock options	113		19					19
Issuance of common stock under Employee Stock Purchase Plan	22		114					114
Interest accrued on notes receivable from stockholders					(16)			(16)
Repayment of notes receivable from stockholders					435			435
Deferred stock compensation			501	(501)				
Amortization of deferred stock compensation				1,400				1,400
Comprehensive loss:								
Change in unrealized loss on marketable securities						(42)		(42)
Cumulative translation adjustment						(5)		(5)
Net loss							(20,555)	(20,555)
Comprehensive loss								(20,602)
	30,482	30	192,840	(2,467)		(149)	(115,891)	74,363

Balances at December 31, 2005						
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)
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 Arrangement			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

*See accompanying notes.*

**Table of Contents**

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

(In thousands)

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Operating activities</b>			
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,483	1,130	759
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc. (SDI)	(8,675)	(9,743)	
Acquired in-process research and development		4,180	
Amortization of intangible assets	1,004	698	
(Gain) loss on disposal of property and equipment		(36)	
Accretion and amortization on marketable securities	(1,855)	(296)	973
Realized loss (gain) on investments		23	(1)
Interest accrued on notes receivable from stockholders			(16)
Interest associated with Deerfield financing agreement	1,248		
Stock-based compensation expense	3,531	3,283	1,400
Changes in operating assets and liabilities:			
Accounts receivable	(5,080)	(976)	2,442
Prepaid expenses and other current assets	(1,851)	604	119
Inventory	257	(257)	
Other assets	1,269	(513)	(10)
Accounts payable	2,237	1,006	(439)
Accrued liabilities	930	5,847	(530)
Deferred revenues	33,441	9,862	(7,000)
Net cash used in operating activities	(32,032)	(37,240)	(22,858)
<b>Investing activities</b>			
Purchases of investments held by SDI	(18,268)	(13,363)	
Cash paid for acquisition, net of cash acquired		(14,045)	
Purchases of marketable securities	(80,232)	(65,842)	(84,014)
Proceeds from maturities of marketable securities	98,550	63,008	59,005
Proceeds from sales of marketable securities		10,987	6,864
Purchases of property and equipment	(3,647)	(1,125)	(562)
Net cash used in investing activities	(3,597)	(20,380)	(18,707)
<b>Financing activities</b>			
Proceeds from purchase of noncontrolling interest by shareholders in SDI, net of fees	30,000	17,405	

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Proceeds from notes payable issued to Deerfield	5,500		
Proceeds from issuance of common stock, net of issuance costs	(19)	44,041	33,137
Exercise of stock options	22	1,340	19
Proceeds from employee stock purchase plan	149	114	114
Repayment of notes receivable from stockholders			435
Net cash provided by financing activities	35,652	62,900	33,705
Effect of exchange rate on cash and cash equivalents	116	149	(5)
Net increase (decrease) in cash and cash equivalents	139	5,429	(7,865)
Cash and cash equivalents at beginning of year	14,154	8,725	16,590
Cash and cash equivalents at end of year	\$ 14,293	\$ 14,154	\$ 8,725
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the year for interest	\$ 356	\$	\$
Non-cash investing and financing activities:			
Liability from program option exercised under the SDI transaction	\$ 15,000	\$	\$
Warrants issued in conjunction with the SDI transaction	\$	\$ 5,646	\$
Warrants issued in conjunction with the Deerfield financing agreement	\$ 9,796	\$	\$
Disposal of fully depreciated property and equipment	\$ 238	\$ 395	\$ 60
Exercise of stock options	\$	\$	\$ 200
Repurchase of common stock for exercise of stock options	\$	\$	\$ (200)

*See accompanying notes.*

**Table of Contents**

**DYNAVAX TECHNOLOGIES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization**

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. 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. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

**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 commercial paper, money market funds, government and non-government debt securities and corporate obligations, which 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.

## **Table of Contents**

Investments held by SDI consist of investments in money market funds. As of December 31, 2007, we had investments held by SDI of \$31.6 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, 2007 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.

## **Fair Value of Financial Instruments**

Carrying amounts of certain of our financial instruments, including cash and cash equivalents, marketable securities, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities.

## **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 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 regulations, uncertainty of market acceptance of products, product liability, and the need to obtain additional financing.

## **Table of Contents**

### **Inventory**

Included in inventory at December 31, 2006 are raw materials and finished goods for a hepatitis B vaccine product. Inventory is stated at the lower of cost or market. Our inventory costs are determined using the first-in, first-out method.

### **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; 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, 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 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.

## **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 are expensed upon the earlier of when non-refundable amounts are due or as services are 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 will be 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 will require 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 will be 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.

## **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 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

## **Table of Contents**

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. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

## **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 11%, 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 employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 5 years. Non-executive level employees were found to have historical option exercise and termination behavior that resulted in an expected life of 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.

## **Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income (loss), which includes certain changes in equity that are excluded from net loss. We include unrealized holding gains and losses on marketable securities and cumulative translation adjustments in accumulated other comprehensive loss.

## **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. income taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2008.



**Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (Issue 07-3), which addressed the accounting for nonrefundable advance payments. The EITF

**Table of Contents**

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. Issue 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 is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008. We do not expect this Issue to have a material effect on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 159 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

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 must adopt SFAS 157 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

**3. 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, 2007 and 2006 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>December 31, 2007:</b>				
Certificates of deposit and money market funds	\$ 42,290	\$	\$	\$ 42,290
Corporate debt securities	44,684	140	(2)	44,822
Total	\$ 86,974	\$ 140	\$ (2)	\$ 87,112
<b>December 31, 2006:</b>				
Certificates of deposit and money market funds	\$ 26,795	\$ 1	\$	\$ 26,796
Corporate debt securities	58,650	27		58,677
Total	\$ 85,445	\$ 28	\$	\$ 85,473

There were no realized gains from the sale of marketable securities for the years ended December 31, 2007 and 2006. Realized losses from the sale of marketable securities were zero in 2007 and immaterial in 2006. As of December 31, 2007 and 2006, all of our investments are classified as short-term, as we have classified our investments as available-for-sale and may not hold our investments until maturity. As of December 31, 2007, our marketable securities had the following maturities (in thousands):

<b>Maturities:</b>	<b>Amortized Cost</b>	<b>Estimated Fair Value</b>
Within 1 year	\$ 86,974	\$ 87,112
Total	\$ 86,974	\$ 87,112

**Table of Contents****4. Inventory**

Inventory as of December 31, 2007 and 2006 consists of the following (in thousands):

	<b>December 31, 2007</b>	<b>December 31, 2006</b>
Raw Materials	\$	\$ 194
Finished Goods		63
Total	\$	\$ 257

**5. Property and Equipment**

Property and equipment as of December 31, 2007 and 2006 consist of the following (in thousands):

	<b>December 31, 2007</b>	<b>December 31, 2006</b>
Laboratory equipment	\$ 12,824	\$ 9,984
Computer equipment	1,403	1,156
Furniture and fixtures	1,525	1,396
Leasehold improvements	2,810	1,968
	18,562	14,504
Less accumulated depreciation and amortization	(11,248)	(9,304)
Total	\$ 7,314	\$ 5,200

Depreciation and amortization expense on property and equipment was \$1.5 million, \$1.2 million and \$0.8 million for the years ended December 31, 2007, 2006, and 2005, 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, 2007 and for the period from April 22, 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 is determined through established valuation techniques in the biotechnology industry. In-process R&D is expensed upon acquisition because technological feasibility has 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)
<b>Total purchase price</b>	<b>\$ 14,558</b>

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 Supervax. 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, 2007 and December 31, 2006 (in thousands, except years):

	Estimated Useful Life (In years)	December 31, 2007			December 31, 2006		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
<b>Intangible Assets:</b>							
Manufacturing process	5	\$ 3,670	\$ 1,244	\$ 2,426	\$ 3,670	\$ 509	\$ 3,161
Customer relationships	5	1,230	417	813	1,230	171	1,059
Developed technology	7				180	18	162

Total	5.1	\$ 4,900	\$ 1,661	\$ 3,239	\$ 5,080	\$ 698	\$ 4,382
-------	-----	----------	----------	----------	----------	--------	----------

**Table of Contents**

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

<b>Year ending December 31,</b>	
2008	\$ 980
2009	980
2010	980
2011	299
Total	\$ 3,239

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):

<b>Program</b>	<b>Description</b>	<b>Estimated Acquisition Date Fair Value</b>
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 therapeutic 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

**Table of Contents**

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 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.

We intend to continue further development of a therapy to treat chronic hepatitis B infection. In March 2007, we initiated a Phase 1 clinical study of our hepatitis B therapeutic candidate in 20 healthy subjects. 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.

**7. Current Accrued Liabilities**

Current accrued liabilities as of December 31, 2007 and 2006 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Payroll and related expenses	\$ 2,892	\$ 1,598
Legal expenses	1,708	732
Third party scientific research expense	6,044	6,668
Other accrued liabilities	1,415	1,744
Total	\$ 12,059	\$ 10,742

**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

**Table of Contents**

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 \$50.0 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.

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 \$74.7 million at the end of the second year of the arrangement, increasing quarterly up to \$144.1 million at the fifth anniversary. 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 \$15.0 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, 2007, the investments held by SDI were \$31.6 million. The investments held by SDI in the consolidated balance sheet include the aggregate \$50.0 million of funding, less funds spent on the Development Programs as of the end of each reporting period.

At December 31, 2007, the noncontrolling interest balance was \$8.3 million. The noncontrolling interest in SDI in the consolidated balance sheet represents Symphony's equity investment in SDI of \$50.0 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 in 2006 and 2007. The noncontrolling interest was further reduced when we recorded the \$15.0 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 \$8.7 million and \$9.7 million for the years ended December 31, 2007 and 2006, 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

**Table of Contents**

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. We will be required to recognize losses incurred by SDI in our consolidated statements of operations after the noncontrolling interest balance has been exhausted.

**9. Financing Agreement**

In July 2007, Deerfield Management, a healthcare investment fund, and its affiliates (Deerfield) committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loan principal for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, we have no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive 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 average share price in the 15-day period prior to achievement of the milestone. Warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive warrants exercisable for the purchase of a total of 5,550,000 shares of the Company's common stock, during the term of the loan agreement.

During the year ended December 31, 2007, we received from Deerfield \$5.5 million in cash which is recorded as a long-term liability in our consolidated balance sheet as of December 31, 2007. In addition, we issued to Deerfield warrants to purchase up to 3,550,000 shares of our common stock; such warrants were valued on the issuance date using the Black-Scholes valuation model. Total warrants issued in connection with the Deerfield financing agreement as of December 31, 2007 and their related assumptions under in the Black-Scholes option valuation model are as follows (in thousands except for Black-Scholes Assumptions):

	Black-Scholes Assumptions				Exercise Price per Share	Assigned Value Using Black-Scholes
	Risk-Free Interest Rate	Expected Life (In Years)	Volatility			
Warrant Issuance Date	Shares Issued	Interest Rate	Life (In Years)	Volatility	Exercise Price per Share	Assigned Value Using Black-Scholes
July 18, 2007	1,250	4.9%	5.5	0.7	\$ 5.13	\$ 3,350
October 18, 2007	1,300	4.2%	5.5	0.7	\$ 5.75	3,700
December 27, 2007	1,000	3.6%	5.5	0.7	\$ 5.65	2,746
Total	3,550					\$ 9,796

At the date of issuance, the warrant valuation is recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost will be amortized on a straight-line basis over the remaining term of the loan and recognized as interest expense in the statement of operations. For the fiscal year ended December 31, 2007, we amortized \$0.8 million of deferred transaction cost in interest expense. Additionally, for the fiscal year ended December 31, 2007 we recognized as interest expense \$0.8 million associated with the commitment fee of which \$0.4 million was paid on January 30, 2008.

## **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

**Table of Contents**

included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. 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, 2007, 2006 and 2005, was \$2.1 million, \$1.8 million and \$1.4 million, respectively. Deferred rent was \$0.2 million as of December 31, 2007.

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 \$25 thousand through 2007 and \$55 thousand annually 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, 2007, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2008	2,073
2009	2,452
2010	2,635
2011	2,693
Thereafter	12,743
<b>Total</b>	<b>\$ 22,596</b>

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. 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.

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 upfront 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, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 million through 2012. 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. Such fees and milestone payments to the Regents could approximate \$1 million in 2008.

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

In October 2007, we entered into a global license and development collaboration agreement with Merck & Co., Inc. (Merck), to jointly develop HEPLISAV, a novel investigational hepatitis B vaccine. Under the terms

**Table of Contents**

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 and will be eligible to receive development cost reimbursement, future development and sales milestone payments up to \$105 million, and royalties on global sales of HEPLISAV. Revenue from the initial payment is deferred and recognized ratably over the contractual term of the collaboration agreement, which is estimated to be 13 years. For the year ended December 31, 2007, we recognized revenue of \$0.4 million related to the upfront fees. Collaboration revenue resulting from the performance of research and development services are recognized as related research and development costs are incurred, as provided for under the terms of these agreements. Cost reimbursement revenue under this collaboration agreement totaled \$5.8 million for the year ended December 31, 2007.

Also in October 2007, we entered into a manufacturing agreement with Merck for the supply of hepatitis B surface antigen. Under the terms of the agreement, we are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck, which is expected to be produced at Dynavax Europe's Düsseldorf, Germany facility using our proprietary technology developed there and later, at our expanded facility to support expected market demand. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV. The October 2007 agreements with Merck are cancelable upon prior written notice to us, following which all rights and licenses to Merck with respect to HEPLISAV will terminate and revert to Dynavax.

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca AB, or AstraZeneca, for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. 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. The financial terms of the collaboration include an upfront fee of \$10 million plus research funding and preclinical milestones that could bring the total committed funding to \$27 million. The total potential deal value including future development milestones approximates \$136 million. Upon commercialization, we are also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$3.1 million for the year ended December 31, 2007. As of December 31, 2007, we recorded deferred revenue of \$10.5 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

In March 2005, we agreed to end our collaboration with UCB Farchim, S.A., or UCB, and regained full rights to our allergy program. During the second quarter of 2005, we received cash payments in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the collaboration. Collaboration revenue for the year ended December 31, 2005 included accelerated recognition of \$7.0 million in deferred revenue as we had no ongoing obligations under the collaboration. Collaboration revenue from UCB amounted to \$12.2 million during the year ended December 31, 2005.

In 2004, we were awarded \$0.5 million from the Alliance for Lupus Research to be received during 2006 and 2007 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 first quarter of 2008. In August 2007, we were awarded a two-year \$3.25 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, 2007, 2006 and 2005, we recognized revenue of approximately \$3.0 million,

\$1.3 million and \$2.2 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.

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Historical (in thousands, except per share amounts):</b>			
Numerator:			
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)
Denominator:			
Weighted-average common shares outstanding	39,746	32,340	25,915
Less: Weighted-average unvested common shares subject to repurchase		(1)	(1)
Denominator for basic and diluted net loss per share	39,746	32,339	25,914
Basic and diluted net loss per share	\$ (1.51)	\$ (1.61)	\$ (0.79)
<b>Historical outstanding dilutive securities not included in diluted net loss per share calculation (in thousands):</b>			
Options to purchase common stock	4,282	3,421	2,599
Warrants	5,550	2,084	84
	9,832	5,505	2,683

**13. Stockholders Equity**

In the fourth quarter of 2005, we sold 5,720,000 shares of common stock in an underwritten public offering, raising net proceeds of approximately \$33.1 million. In the fourth quarter of 2006, we sold 7,130,000 shares of common stock in an underwritten public offering, raising net proceeds of approximately \$29.3 million. Also in the fourth quarter of 2006, we completed a draw down on an equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of common stock.

**Stock Option Plans**

As of December 31, 2007, 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

**Table of Contents**

to all other non-employees. All unvested shares issued under the 1997 Plan are subject to repurchase rights held by the Company under such conditions as agreed to by the Company and the optionee. The 1997 Plan expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

In January 2004, the Board of Directors and stockholders adopted the 2004 Stock Incentive Plan (the 2004 Plan ) which became effective on February 11, 2004. Subsequently, we discontinued granting stock options under the 1997 Plan. The exercise price of all incentive stock options granted under the 2004 Plan must be 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 term of an incentive stock option granted to any other participant must not exceed ten years.

As of December 31, 2007, 4,700,000 shares have been reserved and approved for issuance under the 2004 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:

	<b>Options</b>			
	<b>Available for Grant</b>	<b>Number of Options Outstanding</b>	<b>Weighted-Average Price Per Share</b>	
Balance at December 31, 2006	1,997,141	3,421,339	\$	5.26
Options authorized	400,000			
Options granted	(1,137,085)	1,137,085	\$	5.72
Options exercised		(5,666)	\$	3.86
1997 Plan shares expired	(273,188)			
Options cancelled:				
Options forfeited (unvested)	212,626	(212,626)	\$	5.87
Options expired (vested)	57,677	(57,677)	\$	4.88
Balance at December 31, 2007	1,257,171	4,282,455	\$	5.36

**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, 2007, 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 105,956 shares of our common stock under the Purchase Plan. At December 31, 2007, 390,044 shares of our common stock remained available for future purchases.

### **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

**Table of Contents**

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		
	2007	2006	2005	2007	2006	2005
Weighted-average fair value	\$ 3.53	\$ 4.04	\$ 3.68	\$ 1.96	\$ 2.28	\$ 3.03
Risk-free interest rate	4.7%	4.7%	3.7%	4.6%	4.9%	2.9%
Expected life (in years)	4.5	5.6	4	1.2	1.2	1.2
Volatility	0.8	0.8	0.7	0.7	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 each found to have similar historical option exercise and termination behavior and thus were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

	Years Ended December 31,		
	2007	2006	2005
Employees and directors stock-based compensation expense	\$ 3,462	\$ 3,153	\$ 1,410
Non-employees stock-based compensation expense	69	130	(10)
Total	\$ 3,531	\$ 3,283	\$ 1,400

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, 2007 was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of December 31, 2007, the total unrecognized compensation cost related to non-vested options granted amounted to \$6.8 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.6 years.

Total options exercised during the years ended December 31, 2007, 2006 and 2005 were 5,666, 411,985 and 140,825, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2007, 2006 and 2005 was approximately \$6 thousand, \$1.3 million and 0.8 million, respectively. No income tax benefits have been realized by us in 2007, 2006 and 2005, as we reported an operating loss in each year.

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of December 31, 2007:

Number of	Weighted-Average Exercise Price	Weighted-Average Remaining	Aggregate Intrinsic Value
-----------	------------------------------------	-------------------------------	---------------------------------



	<b>Shares</b>	<b>Per Share</b>	<b>Contractual Term (In years)</b>	<b>(In thousands)</b>
Outstanding options (vested and expected to vest)	3,906,086	\$ 5.30	7.6	\$ 2,556
Options exercisable	1,910,407	\$ 4.68	6.5	\$ 2,321

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

**Table of Contents**

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. Also as a result of adopting FAS 123R, our net loss for the year ended December 31, 2006 is higher by \$2.0 million, than if we had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share for the year ended December 31, 2006 are higher by \$0.06, than if we had continued to account for stock-based compensation under APB 25.

The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of FAS 123 to options granted under our stock-based compensation plans during the year ended December 31, 2005 (in thousands, except per share amounts). For purposes of this pro forma disclosure, the fair value of the options is estimated using the Black-Scholes option valuation model and amortized to expense on a straight-line basis over the vesting periods of the options.

	<b>Year Ended December 31, 2005</b>
Net loss, as reported	\$ (20,555)
Add: Stock-based employee compensation expense included in net loss	1,410
Less: Stock-based employee compensation expense determined under the fair value based method	(2,785)
Net loss, pro forma	\$ (21,930)
Net loss per share:	
Basic and diluted, as reported	\$ (0.79)
Basic and diluted, pro forma	\$ (0.84)

**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 Symphony Dynamo, Inc. before provision for income taxes on a worldwide basis consists of the following (in thousands):

<b>Years Ended December 31,</b>		
<b>2007</b>	<b>2006</b>	<b>2005</b>

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

U.S.	\$ (58,521)	\$ (59,862)	\$ (12,331)
Non U.S.	(1,450)	(1,933)	(8,224)
Total	\$ (59,971)	\$ (61,795)	\$ (20,555)

**Table of Contents**

No income tax expense was recorded for the years ended December 31, 2007, 2006 and 2005 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):

	<b>2007</b>	<b>2006</b>	<b>2005</b>
Income tax benefit at federal statutory rate	\$ (20,390)	\$ (21,045)	\$ (6,989)
State tax	(2,600)	(3,852)	(1,137)
Unbenefited foreign losses		(269)	4,752
Tax credits	(2,594)	(3,088)	(502)
Deferred compensation charges	495	(534)	342
In-process research and development		1,421	
Change in valuation allowance	20,680	27,391	2,872
Change in foreign tax rates	1,966		
Change in NOL	2,356		
Other	87	(24)	662
	\$	\$	\$

Deferred tax assets and liabilities as of December 31, 2007 and 2006 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Deferred tax assets:</b>		
Net operating loss carry forwards	\$ 63,406	\$ 44,278
Research tax credit carry forwards	9,328	5,871
Accruals and reserves	7,067	1,697
Capitalized research costs	8,789	18,582
Other	2,279	277
	90,869	70,705
Less valuation allowance	(89,640)	(68,960)
Total deferred tax assets	\$ 1,229	\$ 1,745
<b>Deferred tax liabilities:</b>		
Other		
Acquired intangible assets	(1,229)	(1,745)
Total deferred tax liabilities	\$ (1,229)	\$ (1,745)
Net deferred tax assets	\$	\$

Management believes that, based on a number of factors, it is more likely than not that the deferred tax assets will not be realized. Accordingly, a full valuation allowance has been recorded for the net deferred tax assets at December 31, 2007 and 2006. The valuation allowance increased by \$20.7 million, \$31.2 million and \$2.9 million during the years ended December 31, 2007, 2006 and 2005, respectively. Approximately \$0.4 million of the valuation allowance for deferred tax assets relates to benefits of stock options deductions that when recognized, will be allocated directly to additional paid in capital.

A provision has not been made at December 31, 2007, 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.

**Table of Contents**

As of December 31, 2007, we had federal net operating loss carryforwards of approximately \$153.5 million and federal research and development tax credits of approximately \$5.5 million, which expire in the years 2011 through 2027. Of these net operating losses, approximately \$19.9 million are attributable to Symphony Dynamo, Inc., which expire in 2027.

As of December 31, 2007, we had net operating loss carryforwards for California state income tax purposes of approximately \$113 million, which expire in the years 2012 through 2026, and California state research and development tax credits of approximately \$5.7 million which do not expire.

As of December 31, 2007, we had net operating loss carryforwards for foreign income tax purposes of approximately \$17.0 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited. The adoption of FIN 48 had no impact on the reported carryforwards at December 31, 2007.

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

	Year Ended December 31, 2007				Year Ended December 31, 2006			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 1,984	\$ 1,800	\$ 1,014	\$ 9,295	\$ 288	\$ 529	\$ 1,592	\$ 2,438
Net loss	\$ (13,090)	\$ (17,704)	\$ (17,101)	\$ (12,076)	\$ (8,172)	\$ (15,273)	\$ (12,152)	\$ (16,455)
Basic and diluted net loss per share	\$ (0.33)	\$ (0.45)	\$ (0.43)	\$ (0.30)	\$ (0.27)	\$ (0.50)	\$ (0.40)	\$ (0.44)
Weighted-average shares used in computing basic and diluted net loss per share(1)	39,727	39,741	39,753	39,765	30,487	30,560	30,605	37,645

(1) The weighted-average shares increased for fourth quarter of 2006 due to the follow on equity offerings that occurred in that period.

**Table of Contents**

**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, 2007. 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**

**Attestation 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, 2007, 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 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, 2007 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2007 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Francisco, California  
March 13, 2008



**(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 2008 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, 2007.

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 is 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

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

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

None, as all required disclosures have been made in the Consolidated Financial Statements and notes thereto.

**(b) Exhibits**

<b>Exhibit Number</b>	<b>Document</b>
3.1(1)	Sixth Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(2)	Registration Rights Agreement.
4.2(2)	Form of Warrant.
4.3(3)	Form of Specimen Common Stock Certificate.
10.19(4)	2004 Non-employee Director Option Program (Revised) and 2005 Non-employee Director Cash Compensation Program, effective April 14, 2005 and amended February 23, 2006.
10.20(5)	Summary of Düsseldorf Lease Agreement as of August 14, 1990, as amended.
10.21(5)	Definitive Commercial Agreement, dated April 21, 2006, among Dynavax Technologies Corporation, Rhein Biotech NV and Rhein Biotech GmbH.
10.22(5)	Exclusive License Agreement, dated April 21, 2006, between Green Cross Vaccine Corp. and Rhein Biotech GmbH.
10.23(5)	Share Sale and Purchase Agreement, dated March 27, 2006, between Dynavax Technologies Corporation and Rhein Biotech N.V.
10.24(5)	License and Supply Agreement, dated February 28, 2002, between Corixa Corporation and Rhein Biotech N.V.
10.25(5)	Purchase Option Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.26(5)	Registration Rights Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.27(5)	Warrant Purchase Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.28(5)	Amended and Restated Research and Development Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.29(5)	Novated and Restated Technology License Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.30(6)	Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and Dynavax Technologies Corporation.
10.31(7)	Underwriting Agreement, dated October 3, 2006.
10.32 (8)	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation.
10.33 (9)	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	Merck Exclusive License and Development Collaboration Agreement, dated October 31, 2007.
10.35	Merck Manufacturing Agreement, dated October 31, 2007.
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.

**Table of Contents**

(1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000-50577).

(2) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

(3) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

(4) 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, 2006, as filed with the SEC.

(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, 2006, 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, 2006, as filed with the SEC.

(7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on October 4, 2006.

(8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC.

(9) 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.

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, Chief Executive Officer and Director  
 (Principal Executive Officer)

Date: March 17, 2008

By: /s/ Deborah A. Smeltzer

Deborah A. Smeltzer  
 Vice President, Operations and  
 Chief Financial Officer  
 (Principal Financial Officer)

Date: March 17, 2008

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Dino Dina, M.D.	President, Chief Executive Officer and Director	March 17, 2008
Dino Dina, M.D.	<i>(Principal Executive Officer)</i>	
/s/ Deborah A. Smeltzer	Vice President, Operations and Chief Financial Officer	March 17, 2008
Deborah A. Smeltzer	<i>(Principal Financial Officer)</i>	
/s/ Arnold Oronsky, Ph.D.	Chairman of the Board	March 17, 2008
Arnold Oronsky, Ph.D.		
/s/ Nancy L. Buc	Director	March 17, 2008
Nancy L. Buc		
/s/ Dennis Carson, M.D.	Director	March 17, 2008
Dennis Carson, M.D.		
/s/ Denise M. Gilbert, Ph.D.	Director	March 17, 2008
Denise M. Gilbert, Ph.D.		
/s/ David M. Lawrence, M.D.	Director	March 17, 2008
David M. Lawrence, M.D.		

/s/ Peggy V. Phillips	Director	March 17, 2008
Peggy V. Phillips		
/s/ Stanley A. Plotkin, M.D.	Director	March 17, 2008
Stanley A. Plotkin, M.D.		