

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 16, 2007

**Table of Contents**

**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-K**

(Mark One)

- b** ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2006
- o** 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: 000-24647**

**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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):  
Large accelerated filer  Accelerated filer  Non-accelerated filer

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, 2006 as reported on the Nasdaq National Market, was approximately \$126,939,241. 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 28, 2007, the registrant had outstanding 39,733,289 shares of common stock.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the registrant's 2007 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>	21
<u>Item 1B.</u>	<u>UNRESOLVED STAFF COMMENTS</u>	31
<u>Item 2.</u>	<u>PROPERTIES</u>	31
<u>Item 3.</u>	<u>LEGAL PROCEEDINGS</u>	31
<u>Item 4.</u>	<u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	31

**PART II**

<u>Item 5.</u>	<u>MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	32
<u>Item 6.</u>	<u>SELECTED FINANCIAL DATA</u>	34
<u>Item 7.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	35
<u>Item 7A.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	46
<u>Item 8.</u>	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	47
<u>Item 9.</u>	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	74
<u>Item 9A.</u>	<u>CONTROLS AND PROCEDURES</u>	74
<u>Item 9B.</u>	<u>OTHER INFORMATION</u>	74

**PART III**

<u>Item 10.</u>	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	75
<u>Item 11.</u>	<u>EXECUTIVE COMPENSATION</u>	75
<u>Item 12.</u>	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	75
<u>Item 13.</u>	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	
<u>Item 14.</u>	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	75

**PART IV**

<u>Item 15.</u>	<u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	75
	<u>SIGNATURES</u>	77

<u>EXHIBIT 21.1</u>	
<u>EXHIBIT 23.1</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	
<u>EXHIBIT 32.2</u>	



**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>™</sup>, a hepatitis B vaccine in Phase 3; TOLAMBA<sup>™</sup>, a ragweed allergy immunotherapy; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca AB, or AstraZeneca. Our preclinical work on a vaccine for influenza is partially funded by the National Institute of Allergy and Infectious Diseases. Our colorectal cancer and hepatitis B therapy trials and our preclinical hepatitis C therapeutic program are funded by Symphony Dynamo, Inc.

***Recent Developments***

***HEPLISAV***

HEPLISAV, our product candidate for hepatitis B prophylaxis, completed a Phase 2 trial conducted in Singapore in adults (40 years of age and older) who are more difficult to immunize with conventional vaccines. Results from the final analysis of this trial showed statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B. We intend to focus our development activities and resources on maximizing the potential of the

**Table of Contents**

demonstrated superiority of HEPLISAV over conventional hepatitis B vaccine in adults, and its potential in the worldwide dialysis market.

In November 2006, we announced results from a Phase 3 trial for HEPLISAV in an older, more difficult-to-immunize population in Asia showing statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B. In December 2006, we announced the results of a Phase 2 trial showing equivalent seroprotection from a shorter two-dose vaccination schedule in subjects 18 to 39 years of age. A U.S.-based Phase 1 trial in patients with end-stage renal disease is ongoing. We have planned additional trials designed to support registration activities. In December 2006, we initiated a pivotal Phase 3 safety and efficacy trial for HEPLISAV in subjects 11 to 55 years of age in Canada followed by the planned initiation of parallel trial sites in the U.S. and Europe in 2007. Also in 2007, we anticipate initiating a Phase 2 trial in the end-stage renal disease population that would be conducted in Europe and/or Canada.

***TOLAMBA***

TOLAMBA (Amb a 1 ISS Conjugate, or AIC) is an injectable product candidate to treat ragweed allergy. In April 2006, we initiated the Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT. The DARTT study was a 30-center, placebo-controlled study that enrolled 738 ragweed allergic subjects, aged 18 to 55 years. The study randomized subjects into three arms: prior dosing regimen; a higher total dose regimen; and placebo. Subjects received six doses of TOLAMBA over six weeks prior to the start of the 2006 ragweed season. In February 2007, we reported that the analysis of interim one-year data from DARTT indicated that no meaningful ragweed-specific allergic disease was observed in the overall study population, making it impossible to measure the therapeutic effect of TOLAMBA treatment. In all three arms of the study, including the placebo arm, minimal change from baseline was observed in the total nasal symptom scores, or TNSS. In the placebo and treated groups, the change from baseline TNSS was very low, not clinically significant, and substantially lower than what has been observed in prior trials. Entry criteria for the DARTT study, including a clinical history of ragweed allergy and a confirmatory skin test did not reproducibly select patients with moderate to severe disease. The same enrollment criteria were used in a 313-subject clinical trial of TOLAMBA in ragweed allergic children, the primary endpoint of which was improvement in allergy symptoms following the second (2006) ragweed season. The results of the pediatric trial showed an even lower incidence of ragweed-specific allergic disease in children. Given the low level of disease in the trials' study populations, we believe the planned second and third year follow-up analyses for DARTT and the pediatric trial are unlikely to yield valuable data, and as a result, we have decided to discontinue both studies.

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

Results from a two-year Phase 2 clinical trial of TOLAMBA showed that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores and other efficacy endpoints compared to placebo-treated patients in the trial. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

We are currently in the process of evaluating the feasibility of new trial designs, defining a regulatory path, and projecting the timeline and costs, including partnership opportunities, associated with advancing the TOLAMBA program.



***Symphony Dynamo, Inc.***

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer therapy, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, Symphony Dynamo, Inc. (SDI)

## **Table of Contents**

agreed to invest \$50.0 million to fund the clinical development of these programs and we licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We are primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, representing a 25% premium over the 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. 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. In consideration for the warrant, we received an exclusive purchase option to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. The purchase option exercise price is payable in cash or a combination of cash and shares of our common stock, at our sole discretion. We also have an option to purchase either the hepatitis B or hepatitis C program during the first year of the agreement. The program option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the purchase option. If we do not exercise our exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

In cancer, 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. In December 2006, we initiated a Phase 1 dose escalation clinical trial of our cancer product candidate in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. In March 2007, we initiated a Phase 1 trial of our therapy for chronic hepatitis B virus (HBV) infection. We anticipate that additional cancer product candidates will advance into clinical trials in solid tumors in 2007, and our hepatitis C therapeutic product candidate is also planned to enter the clinic in 2007.

### ***ISS for Non-Hodgkin's Lymphoma***

We have an ongoing Phase 2 study in non-Hodgkin's lymphoma, or NHL, of ISS in combination with Rituximab (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. Patients treated with the combination therapy showed a prolonged time to progression as compared to patients who were less responsive to the drug and to historical controls. 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.

### ***AstraZeneca Research Collaboration and License Agreement***

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.

### ***Influenza Vaccine***

In the fourth quarter of 2006, we announced preclinical data that show our influenza (flu) vaccine can improve the immunogenicity of standard flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with standard vaccine enhances the immune response of the standard

**Table of Contents**

vaccine, allows reduction of standard vaccine dosage, and provides extra layers of protection that are not strain-dependent. Our flu vaccine is based on our proprietary TLR9 agonist-based ISS technology. The preclinical work was funded in part by a research and development grant for a pandemic flu vaccine from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health.

**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.

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

## **Table of Contents**

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. We are using a proprietary ISS, a 22-base synthetic DNA molecule called 1018 ISS, in our clinical development programs for ragweed allergy, hepatitis B prophylaxis, asthma and cancer. 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.

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

## **Table of Contents**

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 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 can 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 Hepatitis B Products, Allergy Immunotherapy, Cancer and Chronic Inflammation, as described below.

#### **Hepatitis B Products**

##### **Hepatitis B Prevention**

##### ***HEPLISAV: Our Hepatitis B Vaccine Product Candidate and its Benefits***

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 immunizations over two months 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 traditionally responds poorly to current vaccines. Therefore, we believe HEPLISAV may offer an efficacy advantage versus currently available vaccines for patients that are traditionally difficult to immunize, including pre-dialysis, HIV or HCV infected individuals.

Our commercial strategy for HEPLISAV is designed to target high-value, high-risk patient populations whose need for rapid and effective protection against HBV is urgent and who are underserved by conventional vaccines. We are initially focusing on patients with chronic renal failure who are either about to undergo hemodialysis or are already on

hemodialysis, and who are at substantial risk for HBV infection. We also intend to focus on people with HIV and hepatitis C infections for whom co-infection with HBV is a serious concern. We believe that healthcare workers and emergency personnel, who face significant occupational risks of infection, as well as discretionary travelers, also represent important potential markets for HEPLISAV.



**Table of Contents**

*Clinical Status*

Results from Phase 1 and from Phase 2 trials showed that HEPLISAV was well tolerated and induced more rapid immunity with fewer immunizations in both healthy young and older adults than GlaxoSmithKline's Engerix-B. Our Phase 1 trial investigated the effects of escalating doses of ISS, from 0.3 mg to 3.0 mg, in each case administered with the same amount of hepatitis B surface antigen as used in conventional vaccines. In this trial we enrolled 48 subjects and demonstrated that all subjects who received two injections of at least 0.65 mg ISS with hepatitis B surface antigen achieved protective hepatitis B antibody responses. We conducted a Phase 2 trial in Canada evaluating the efficacy of two injections of HEPLISAV (hepatitis B surface antigen plus 3.0 mg of 1018 ISS) 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 injection and protective hepatitis B antibody response in 100% of recipients after the second injection at two months. In contrast, subjects receiving Engerix-B had protective hepatitis B antibody responses after the first and second injections in 12% and 64% of recipients, respectively.

We completed a Phase 2 trial in Singapore that evaluated the efficacy of our vaccine in older subjects (ages 40-70 years) who have a diminished ability to respond to current commercial vaccines. Results showed superiority of HEPLISAV compared to Engerix-B relative to the primary efficacy endpoint of seroprotection (100% seroprotection in the HEPLISAV-treated group compared to 90.5% in the Engerix-B treated group;  $p=0.034$ ) and relative to geometric mean concentration or GMC (1698 compared to 569 mIU/mL;  $p=0.023$ ). Results also showed that subjects treated with HEPLISAV experienced more durable seroprotection. At week 50, the HEPLISAV-treated group measured 100% seroprotection and GMC of 499 mIU/mL compared to 86% and 153 mIU/mL for the Engerix-B treated group ( $p=0.009$  and  $p=0.005$ , respectively). The primary endpoint of the trial was seroprotection following three doses, and a key secondary endpoint was GMC, a measure of the robustness of antibody response. The safety profile of the vaccine was highly favorable.

In November 2006, we announced results from a Phase 3 trial for HEPLISAV in an older, more difficult-to-immunize population in Asia showing statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to Engerix-B. The data showed that after three doses, HEPLISAV provided seroprotection to 100% of subjects versus 73.1% for Engerix-B ( $p < 0.0001$ ). The greatest difference in seroprotection after three doses was seen in subjects 56 to 70 years of age where HEPLISAV provided 100% seroprotection and Engerix-B provided 56.1%. Data for the entire study population showed that after two doses, HEPLISAV provided 98.5% seroprotection versus Engerix-B's 25%. Furthermore, HEPLISAV provided a level of immunity as measured by geometric mean concentrations of anti-HBsAg antibodies 18.5 times higher than Engerix-B four weeks after the third dose. The Phase 3 trial enrolled more than 400 seronegative subjects, 40 to 70 years of age, at study sites in Singapore, Korea and the Philippines. One group of subjects received three doses of HEPLISAV; the other group received three doses of Engerix-B.

In December 2006, we announced the results of a Phase 2 trial showing equivalent seroprotection from a shorter two-dose vaccination schedule in the younger adult population. The data showed that 100% seroprotection is achieved whether the second dose is administered one or two months after the first. 100% of all subjects were seroprotected at month three and all subjects sustained seroprotection at month eight. HEPLISAV was found to be safe and well tolerated. The Phase 2 trial enrolled more than 40 seronegative subjects, 18 to 39 years of age, at one study site in Canada. One group of subjects received HEPLISAV at 0 and 1 month; the other group received HEPLISAV at 0 and 2 months.

A U.S.-based Phase 1 trial in patients with end-stage renal disease is ongoing. We have planned additional trials designed to support registration activities. In December 2006, we initiated a pivotal Phase 3 safety and efficacy trial

for HEPLISAV in subjects 11 to 55 years of age in Canada followed by the planned initiation of parallel trial sites in the U.S. and Europe in 2007. Also in 2007, we anticipate initiating a Phase 2 trial in the end-stage renal disease population that would be conducted in Europe and/or Canada.

**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, there are large numbers of individuals, born prior to the implementation of these programs, who 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.

***SUPERVAX***

In April 2006, we completed the acquisition of Rhein Biotech GmbH, which we refer to as Dynavax Europe. As a result, we acquired a hepatitis B vaccine called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection when administered on a two-dose schedule. SUPERVAX was launched in Argentina in December 2006 and is approved for marketing and sales through a third party partner. We intend to continue registration activities for SUPERVAX as a two-dose vaccine for adolescents for commercialization through partners in select countries outside of North America and Europe.

***Current Hepatitis B Vaccines and their Limitations***

Current hepatitis B vaccines consist of a three-dose immunization regimen administered over six months. If completed, current hepatitis B vaccination confers protective hepatitis B antibody responses to approximately 95% of healthy young adults. However, the protective hepatitis B antibody responses achieved by conventional vaccines is lower for persons who are immunocompromised. Additionally, there is an inversely proportional relationship between age and the degree to which current vaccines confer protective hepatitis B antibody responses: the older you are, the less effective current vaccines are. Compliance with the immunization regimen is also a significant issue, as many patients fail to receive all three doses. According to a survey of U.S. adolescents and adults published by the Centers for Disease Control, of those who received the first dose of vaccine, only 53% received the second dose of vaccine and only 30% received the third. We believe that compliance rates in other countries are similar or worse. For healthy young adults, protective hepatitis B antibody responses after the first dose are reported to be between 10% and 12% and improve to only 38% to 56% after the second dose. Consequently, an unacceptably large number of individuals who start the immunization series remain susceptible to infection. Poor field efficacy is of particular concern in regions with high hepatitis B prevalence and constitutes a major public health issue.

***Hepatitis B Therapy***

***Benefits of our Approach to Hepatitis B Therapy***

Our 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.

***Clinical Status***

In March 2007, we initiated a Phase 1 trial of our therapy for chronic HBV infection. We intend to enroll 20 healthy subjects to evaluate the safety of the therapy at two dosing schedules. The therapy combines the surface and core antigen of HBV manufactured at Dynavax Europe. The trial is funded by SDI and we anticipate results from the trial in the second half of 2007.

***Commercial Opportunity***

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. There is a large population chronically infected with

## **Table of Contents**

hepatitis B, including an estimated one million patients in the U.S., two million in Europe, nine million in Japan and three hundred fifty million in the rest of the world. In many countries in Southeast Asia and the Pacific Basin, HBV endemicity is as high as 20-25% of the population.

### ***Currently Available Hepatitis B Therapies and their Limitations***

Currently available therapies for chronic hepatitis B infection include interferon alpha and antiviral drugs. Interferon-alpha has been shown to normalize liver enzyme function in approximately 40% of individuals treated. The approved antiviral drugs, which work by inhibiting viral replication, reduce hepatitis B viral load approximately 3,000-fold and normalize liver enzymes in 50% to 75% of patients. However, in most cases the hepatitis B virus reappears when the antiviral drugs are discontinued. Both interferon-alpha and antiviral drugs are expensive and may induce significant side effects. In addition, patients typically become resistant to antiviral drugs as early as one year after initiating treatment, potentially rendering them ineffective as long-term therapies.

## **Allergy Immunotherapy**

### **Ragweed Allergy**

#### ***TOLAMBA for Ragweed Allergy and its Benefits***

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***

Over the last several years, TOLAMBA has been tested in fifteen clinical trials in the U.S., France and Canada, and more than 7,000 TOLAMBA injections have been administered to more than 1,100 patients. In these trials, TOLAMBA was shown to be safe and well-tolerated.

In April 2006, we initiated the Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT. The DARTT study was a 30-center, placebo-controlled study that enrolled 738 ragweed allergic subjects, aged 18 to 55 years. The study randomized subjects into three arms: prior dosing regimen; a higher total dose regimen; and placebo. Subjects received six doses of TOLAMBA over six weeks prior to the start of the 2006 ragweed season. In February 2007, we reported that the analysis of interim one-year data from DARTT indicated that no meaningful ragweed-specific allergic disease was observed in the overall study population, making it impossible to measure the therapeutic effect of TOLAMBA treatment. In all three arms of the study, including the placebo arm, minimal change from baseline was observed in the TNSS. In the placebo and treated groups, the change from baseline TNSS was very low, not clinically significant, and substantially lower than what has been observed in prior trials. Entry criteria for the DARTT study, including a clinical history of ragweed allergy and a confirmatory skin test did not reproducibly select patients with moderate to severe disease. The same enrollment criteria were used in a 313-subject clinical trial of TOLAMBA in ragweed allergic children, the primary endpoint of which was improvement in allergy symptoms following the second (2006) ragweed season. The results of the pediatric trial showed an even lower incidence of ragweed-specific allergic disease in children. Given the low level of disease in the trials' study populations, we believe the planned second and third year follow-up analyses for DARTT and the pediatric trial are unlikely to yield valuable data, and as a result, we

have decided to discontinue both studies.

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

## **Table of Contents**

benefit of TOLAMBA in reducing total nasal symptom scores was evident, as reflected in a clinically meaningful reduction of TNSS in the treated patients. The data provide a rationale for continuing to evaluate our TLR9-based approach for treating ragweed and other allergic diseases.

Results from a two-year Phase 2 clinical trial of TOLAMBA showed that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores and other efficacy endpoints compared to placebo-treated patients in the trial. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

We are currently in the process of evaluating the feasibility of new trial designs, defining a regulatory path, and projecting the timeline and costs, including partnership opportunities, associated with advancing the TOLAMBA program.

### ***Commercial Opportunity***

Medical management of seasonal allergic rhinitis is a multibillion-dollar global market. In the U.S. alone, approximately 40 million people suffer from allergic rhinitis. The direct costs of prescription interventions for allergic rhinitis in the U.S. were \$8 billion in 2004. Ragweed is the single most common seasonal allergen, affecting up to 75% of those with allergic rhinitis, or 30 million Americans. In addition, 20-30% of those who suffer from allergic rhinitis progress to asthma, leading to increased morbidity and disease management costs. We believe that a significant market opportunity exists for TOLAMBA in the treatment of ragweed allergic individuals currently undergoing conventional immunotherapy or using multiple prescription or over-the-counter (OTC) medications. In addition, the product may also play a role in earlier stage disease, potentially preventing the allergic march from allergic rhinitis to asthma.

### ***Current Allergy Treatments and their Limitations***

***Drug Treatments*** Many individuals turn to prescription and OTC pharmacotherapies such as antihistamines, corticosteroids, anti-leukotriene agents and decongestants to manage their allergy symptoms. Although currently available pharmacotherapies may provide temporary symptomatic relief, they can be inconvenient to use and can cause side effects. Most importantly, these pharmacotherapies need to be administered chronically and do not modify the underlying disease state.

***Allergy Shots (Immunotherapy)*** Allergy shots, or immunotherapy, are employed to alter the underlying immune mechanisms that cause allergic rhinitis. Patients are recommended for allergy immunotherapy only after attempts to reduce allergic symptoms by drugs or limiting exposure to the allergen have been deemed inadequate. Conventional immunotherapy is a gradual immunizing process in which increasing individualized concentrations of 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.

**Other Allergy Immunotherapy Candidates**

We may produce similar ISS-allergen linked product candidates for the treatment of other major allergies. Each of grass, birch and cedar-induced seasonal allergic rhinitis is caused by an allergic immune system response to identified and characterized allergens. Consequently, product candidates for each can be produced in a manner similar to TOLAMBA. For example, the major grass allergens, Lol p 1 and Ph1 p 5, and the



## **Table of Contents**

major cedar tree allergens, Cry j 1 and Cry j 2, can be linked to ISS. We believe our approach may provide distinct advantages over conventional immunotherapy for these allergies, including a potentially favorable safety profile, significantly shorter dosing regimen and long-term therapeutic benefits.

We believe that our additional allergy products may present the same advantages over symptomatic interventions as described for TOLAMBA. As a result of these advantages and by providing a broader set of allergy immunotherapies, we may ultimately achieve an expansion into the large group of patients that currently choose pharmacotherapies over existing immunotherapies.

## **Peanut Allergy**

### ***ISS for Peanut Allergy and its Benefits***

We believe that ISS linked with a major peanut allergen, Ara h 2, may be able to suppress the Th2 response and reduce or eliminate the allergic reaction without inducing anaphylaxis during the course of immunotherapy. 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 due to accidental exposure to peanuts.

### ***Preclinical Status***

We have developed a peanut allergy product candidate that consists of ISS linked to a major peanut allergen, Ara h 2. 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. ISS-linked Ara h 2 also induces much higher levels of interferon-gamma and much lower levels of IL-5 than unmodified Ara h 2 in mice. Immunization with our product candidate has also been shown to protect peanut allergic animals from anaphylaxis and death following exposure to peanut allergen. In addition, we have demonstrated that ISS-linked Ara h 2 has significantly reduced allergic response as measured by in vitro histamine release assays using blood cells from peanut allergic patients.

### ***Commercial Opportunity***

Peanut allergy accounts for the majority of severe food-related allergic reactions. 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.

### ***Current Peanut Allergy Treatments and their Limitations***

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 immunotherapy is designed to allow patients to tolerate exposure to higher levels of peanut products without experiencing severe reactions.

## **Cancer Therapy**

### ***Benefits of our Approach to Cancer Therapy***

We are developing 1018 ISS and second generation TLR9 agonists as a potential therapy for cancer. TLR9 plays a central role in immune regulation and has multiple actions that indicate a potentially significant role in cancer therapy. These include production of interferons (IFN) and other cytokines such as TNF- and IL-12 and activation of macrophages and NK cells.

## **Table of Contents**

ISS has the potential to become a versatile cancer therapy that could be used broadly. 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. This has been demonstrated in Phase 1 and Phase 2 studies in NHL patients conducted by Dynavax and its collaborators.

### ***Clinical Status***

In December 2006, we initiated a Phase 1 dose-escalation clinical trial of our TLR9 agonist in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. The enrollment target of the trial is 15 patients, all of whom will have been previously treated for colorectal cancer but had a recurrence of the disease. The trial, which will be conducted at three centers in the United States, is designed to identify the optimum dose and to yield safety and tolerability data for escalating doses of our TLR9 agonist administered with irinotecan and cetuximab. We anticipate that the trial, funded by SDI, will be completed in the first half of 2007. We plan to use the data to design a larger Phase 2 multi-center, randomized controlled trial in metastatic colorectal cancer, which we anticipate initiating in 2007.

An ongoing Phase 2 trial funded by the National Institutes of Health is evaluating the use of ISS in combination with rituximab as a treatment for patients with non-Hodgkin's lymphoma. In December 2006, we announced preliminary data from the study which enrolled 23 follicular lymphoma patients who had relapsed after at least one prior treatment. Patients treated with the combination therapy showed a prolonged time to progression as compared to patients who were less responsive to the drug and to historical controls. The combination of rituximab and ISS was well-tolerated, and adverse events were minimal. We previously reported a Phase 1, dose-escalation trial of ISS in combination with rituximab in 20 patients with non-Hodgkin's lymphoma. In this trial, dose-dependent pharmacological activity was demonstrated without significant toxicity.

### ***Commercial Opportunity***

Cancer remains one of the areas of greatest unmet medical need in medicine today. Annually, over 1.3 million people are diagnosed with cancer and over 500,000 people die of the disease, making cancer the second leading cause of death in the U.S. Current therapies for cancer include surgery, chemotherapy and radiation as well as targeted agents such as antibodies and hormonal therapies. Surgery and radiation are limited to the site of the initial tumor; chemotherapy causes severe side effects and has limited effect, with high rates of recurrence. Major unmet medical needs exist for new cancer treatments that offer higher rates of efficacy with fewer side effects and that can be used alone or in combination with other therapies. ISS has the potential to become a versatile cancer therapy that could be used broadly, in multiple tumor types, alone or in combination with established standards of care. ISS has an excellent safety profile and is administered via simple subcutaneous administration, an improvement over most chemotherapy and monoclonal antibody approaches that require IV infusion.

### **Chronic Inflammation**

#### **Asthma**

#### ***Inhaled ISS for Asthma and its Benefits***

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

## **Table of Contents**

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.

### ***AstraZeneca Research Collaboration and License Agreement***

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.

### **Additional Programs**

In addition to our primary product portfolio, we are pursuing earlier stage programs in Next-Generation Vaccines and Autoimmune Disorders, as described below.

#### **Next-Generation Vaccines**

##### ***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 20,000 viral flu-associated deaths per year. Pandemics occur infrequently, on average every 33 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 reconfigured and administered annually. Our approach links advanced ISS to conserved flu antigens. We believe that ISS-linked conserved antigens added to conventional vaccine will not only increase antibody responses capable of blocking viral infections but also confer protective immunity against divergent flu strains. In the fourth quarter of 2006, we announced preclinical data that show our flu vaccine can improve the immunogenicity of standard flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with standard vaccine enhances the immune response of the standard vaccine, allows reduction of standard vaccine dosage, and provides extra layers of protection that are not strain-dependent. In the third quarter of 2003 we were awarded a \$3.0 million grant over three and a half years to fund research and development of an advanced pandemic flu vaccine under an NIAID program for biodefense administered by the National Institutes of Health.

##### ***Anthrax Vaccine***

We are using our advanced ISS technology to develop an improved anthrax vaccine that we expect will be well tolerated and provide protective immunity after one or two immunizations. The only available anthrax vaccine, Anthrax Vaccine Adsorbed, or AVA, was approved in the U.S. in 1970 and has been used extensively by the military. The vaccine has been reported to cause relatively high rates of local and systemic adverse reactions. In addition, the administration of AVA requires six subcutaneous injections over 18 months with subsequent annual boosters. Our vaccine candidate will be composed of recombinant anthrax protective antigen, or rPA, combined with advanced ISS enhanced by a proprietary formulation. The use of advanced ISS in this formulation should enhance both the speed and magnitude of the antibody response developed against rPA compared to AVA and other rPA-based products in

development. Preclinical experiments have demonstrated that rPA combined with our advanced ISS formulations has generated significantly higher toxin neutralizing antibody responses compared to rPA alone or rPA combined with the standard vaccine adjuvant, alum in mouse and monkey models. In addition, the rPA combined with advanced ISS formulations has provided protection from respiratory anthrax spore challenge in mouse, guinea pig, and rabbit models. In the third quarter of 2003, the National Institute of Allergy and Infectious Diseases, or NIAID, awarded us a

## **Table of Contents**

\$3.6 million grant over three and a half years to fund research and development of an advanced anthrax vaccine as part of its biodefense program.

### ***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 disease, including systemic lupus erythematosus (SLE or lupus). Based upon this initial research, in the fourth quarter of 2004, the Alliance for Lupus Research (ALR) awarded us a \$0.5 million grant over two years to explore new treatment approaches for SLE based on our IRS technology.

### **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 48 issued U.S. and foreign patents, 31 pending U.S. patent applications, and 91 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 7 pending U.S. and foreign patent applications providing worldwide rights to certain compositions and methods using IRS (including immunoinhibitory sequences). We hold exclusive, worldwide licenses to these patents and patent applications held by the Regents of the University of California.

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

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies, biotechnology companies, including Coley Pharmaceutical Group, or Coley, 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



## **Table of Contents**

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. Coley 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 HEPLISAV. We may enter into manufacturing agreements with one or more commercial-scale contract manufacturers to produce additional supplies of HEPLISAV as required for new clinical trials and commercialization, or we may have to establish internal commercial-scale manufacturing capability for HEPLISAV, incurring increased capital and operating costs, delays in the commercial development of HEPLISAV and higher manufacturing costs than we have experienced to date.

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

## **Table of Contents**

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-injection vaccine products produced by Merck & Co., Inc., or Merck; GlaxoSmithKline plc, or GSK; and Crucell N.V., among others. There are also two-injection hepatitis B vaccine products in clinical development, including a vaccine being developed by GSK which has been approved for marketing in the European Union. In addition, HEPLISAV will compete against a number of multivalent vaccines that simultaneously protect against hepatitis B in addition to other diseases. Our hepatitis B immunotherapy, 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.

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, Curalogic 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 TLR9 agonist therapy for cancer, if approved and commercialized, will compete directly with other immune therapies such as those in development by Coley/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, 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 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 Coley. 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.

## **Table of Contents**

### **Regulatory Considerations**

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

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

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

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

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

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

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

To secure FDA approval, we must submit extensive non-clinical and clinical data, manufacturing information, and other supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. The number of preclinical studies and clinical trials that will be required for FDA and foreign regulatory agency approvals varies depending on the product candidate, the disease or condition for which the product candidate is in development and regulations applicable to any particular drug candidate. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval or clearance. Further, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. The approval process takes many years, requires the expenditures of substantial resources, involves post-marketing surveillance and may involve requirements for additional post-marketing studies. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. The FDA may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing. Delays experienced during the governmental approval process may materially reduce the period during which we will have exclusive rights to 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;

**Table of Contents**

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

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

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

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

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



## **Table of Contents**

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 February 28, 2007, we had 153 full-time employees, including 29 Ph.D.s, 4 M.D.s and 16 others with advanced degrees. Of the 153 employees, 119 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement, and we believe our relations with our employees are good.

## **Available Information and Website Address**

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

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

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

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

We have experienced significant operating losses in each year since our inception. Our accumulated deficit was \$167.9 million as of December 31, 2006. 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 will terminate in 2007. We anticipate that we will incur substantial additional operating losses for the foreseeable future as the 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.

**Table of Contents**

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 regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.**

None of our TLR9 product candidates has 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.

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. For example, our decision to discontinue the DARTT and pediatric studies of TOLAMBA will have a significant impact on the timing and potential cost for potential approval of TOLAMBA in the treatment of ragweed allergies if further development efforts are initiated.

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;

**Table of Contents**

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 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 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 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 1018 ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

**result in additional costs, which could preclude us from manufacturing our product candidates on commercially reasonable terms.**

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.

**Table of Contents**

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 pass a pre-approval inspection before we can obtain regulatory approval 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 HEPLISAV. We may enter into manufacturing agreements with one or more commercial-scale contract manufacturers to produce additional supplies of HEPLISAV as required for new clinical trials and commercialization, or we may have to establish internal commercial-scale manufacturing capability for HEPLISAV, incurring increased capital and operating costs, delays in the commercial development of HEPLISAV and higher manufacturing costs than we have experienced to date.

**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.

We intend to seek partners for purposes of commercialization of HEPLISAV in selected markets worldwide. Marketing challenges vary by market and could limit or delay acceptance in any particular country. We believe that market acceptance of HEPLISAV will depend on our ability to offer increased efficacy and improved ease of use as compared to existing or potential new hepatitis B vaccine products.

**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



**Table of Contents**

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.

**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, notably HEPLISAV, in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the



**Table of Contents**

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;

the fluctuation of conversion rates between foreign currencies and the U.S. dollar; 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 recently acquired Rhein Biotech GmbH and any difficulties from integrating Rhein's business into ours could disrupt our business and harm our financial condition.**

In April 2006, we acquired Rhein Biotech GmbH. Through this acquisition, we gained ownership of a European Union (EU) GMP-certified vaccine manufacturing facility in Düsseldorf, Germany, certain vaccine and other commercial programs, a management team and personnel with specialized expertise in process development and vaccine manufacturing. Integrating Rhein's operations, technology and personnel with our operations and personnel is a complex process. The successful integration of Dynavax and Rhein requires, among other things, ongoing coordination of various integration efforts, relating to our personnel system, technologies and commercial programs. We may not be able to rapidly or efficiently integrate Rhein's business and technology into ours and the expected benefits of the combination may not materialize. Our ability to successfully integrate Rhein involves numerous risks, including:

difficulties in integrating the operations, technologies, products and personnel of Rhein, including achieving compliance with the requirements under Section 404 of the Sarbanes-Oxley Act of 2002 by the end of 2007;

difficulties in successfully utilizing Rhein's manufacturing capabilities to produce materials for our existing product candidates in lieu of purchasing such materials from third party vendors;

diversion of management's attention from normal daily operations of the business;

potential difficulties in integrating different projects;

difficulties in entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;

insufficient revenues to offset increased expenses associated with the acquisition; and

potential loss of key employees of Rhein.

There can be no assurance that we will be able to successfully integrate Rhein and its technology and personnel into our business.

**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.

## **Table of Contents**

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. If we become involved in any litigation, interference or other administrative proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors relative to HEPLISAV, Merck and GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen. In addition, the Institute Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside of the United States, they remain in force in the United States and are likely to be in force when we commercialize HEPLISAV or a similar product in the United States. To the extent we are able to commercialize HEPLISAV in the United States while these patents are issued, Merck and/or GSK or the Institute Pasteur may bring claims against us.

If we are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against us, for example, as may arise to the extent we were to commercialize HEPLISAV or any similar product candidate in the United States, we could be required to pay substantial damages and we may be unable to commercialize our product candidates or use our proprietary technologies unless we obtain a license from these or other third parties if a license is available at all. A license may require us to pay substantial fees or royalties, require us to grant a cross-license to our technology or may not be available to us 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.

Another of our potential competitors, Coley, 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 claims held by Coley 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. 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.

**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.

**Table of Contents**

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. For example, we expect to market HEPLISAV, if approved, in various foreign countries with high incidences of hepatitis B, including Canada, Europe and selected markets in Asia, 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.

**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 the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise this 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 this option in a timely manner.**

In 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapeutics to Symphony Dynamo, Inc., or SDI, in consideration for a commitment from Symphony Capital Partners, LP and its co-investors to provide \$50 million of committed capital to advance these programs. As part of the arrangement, we received an option granting us the exclusive right, but not the obligation, to acquire certain or all of the programs at specified points in time at specified prices during the term of the five-year development period. The development programs under the arrangement are jointly managed by SDI and us, 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



## **Table of Contents**

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 option. If we do not exercise the purchase option prior to its expiration, then our rights in and with respect to the SDI 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, which at our election may be paid partially in shares of our common stock. As a result, in order to exercise the 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 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 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. In addition, the exercise of the purchase option will likely require us to record a significant charge to earnings and may adversely impact future operating results.

### **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

**Table of Contents**

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 collaborations for the development and commercialization of our product candidates;

our ability to raise additional capital to fund our operations;

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

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

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

our ability to enter into 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;

## **Table of Contents**

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.

**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, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. 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. Specifically, with the Rhein acquisition, our foreign operations will be part of our operations for Section 404 compliance. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control reporting. If we are unable to maintain an unqualified attestation as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

We lease approximately 67,000 square feet of laboratory and office space in Berkeley, California (the Berkeley Lease) under agreements expiring in September 2014, of which approximately 13,000 square feet is subleased through August 2007. 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 3,500 square meters of laboratory and office space in Düsseldorf, Germany, (the Düsseldorf Lease) under lease agreements expiring in August 2009.

### **ITEM 3. LEGAL PROCEEDINGS**

None.

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

None.

31

---

**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>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
<b>2005</b>		
First Quarter	\$ 8.48	\$ 4.50
Second Quarter	\$ 4.97	\$ 3.44
Third Quarter	\$ 7.00	\$ 4.61
Fourth Quarter	\$ 6.75	\$ 3.89

As of February 28, 2007, there were approximately 102 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 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 LP we issued to Symphony 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.



**Table of Contents**

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, 2006, 2005 and 2004 and the Consolidated Balance Sheets Data as of December 31, 2006 and 2005 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, 2003 and 2002 and the Consolidated Balance Sheets Data as of December 31, 2004, 2003 and 2002 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.

	2006 (1)	Years Ended December 31,			2002
		2005	2004	2003	
		(In thousands, except per share data)			
<b>Consolidated Statements of Operations Data:</b>					
Total revenues	\$ 4,847	\$ 14,655	\$ 14,812	\$ 826	\$ 1,427
Operating expenses:					
Research and development	50,116	27,887	23,129	13,786	15,965
General and administrative	14,836	9,258	8,543	4,804	4,121
Acquired in-process research and development	4,180				
Amortization of intangible assets	698				
Total operating expenses	69,830	37,145	31,672	18,590	20,086
Loss from operations	(64,983)	(22,490)	(16,860)	(17,764)	(18,659)
Interest and other income, net	3,188	1,935	889	412	621
Deemed dividend				(633)	
Loss including noncontrolling interest in Symphony Dynamo, Inc.	\$ (61,795)	\$ (20,555)	\$ (15,971)	\$ (17,985)	\$ (18,038)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	9,743				
Net loss	\$ (52,052)	\$ (20,555)	\$ (15,971)	\$ (17,985)	\$ (18,038)
Basic and diluted net loss per share	\$ (1.61)	\$ (0.79)	\$ (0.75)	\$ (10.04)	\$ (10.65)
Shares used in computing basic and diluted net loss per share	32,339	25,914	21,187	1,791	1,694

- (1) Our net loss for the year ended December 31, 2006 includes approximately \$2.0 million 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.

	2006	2005	December 31, 2004 (In thousands)	2003	2002
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents and marketable securities	\$ 72,831	\$ 75,110	\$ 65,844	\$ 29,097	\$ 29,410
Investments held by Symphony Dynamo, Inc.	13,363				
Working capital	75,985	71,941	64,017	26,340	25,913
Total assets	102,890	80,093	73,646	31,585	31,478
Noncontrolling interest in Symphony Dynamo, Inc.	2,016				
Minority interest in Dynavax Asia				14,733	
Convertible preferred stock				83,635	83,635
Accumulated deficit	(167,943)	(115,891)	(95,336)	(79,365)	(62,013)
Total stockholders' equity (net capital deficiency)	77,056	74,363	59,876	(71,932)	(56,371)

**Table of Contents**

**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<sup>™</sup>, a hepatitis B vaccine in Phase 3; TOLAMBA<sup>™</sup>, a ragweed allergy immunotherapy; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca. Our preclinical work on a vaccine for influenza is partially funded by the National Institute of Allergy and Infectious Diseases. Our colorectal cancer and hepatitis B therapy trials and our preclinical hepatitis C therapeutic program are funded by Symphony Dynamo, Inc.

**Recent Developments**

***HEPLISAV***

HEPLISAV, our product candidate for hepatitis B prophylaxis, completed a Phase 2 trial conducted in Singapore in adults (40 years of age and older) who are more difficult to immunize with conventional vaccines. Results from the final analysis of this trial showed statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B. We intend to focus our development activities and resources on maximizing the potential of the demonstrated superiority of HEPLISAV over conventional hepatitis B vaccine in adults, and its potential in the worldwide dialysis market.

In November 2006, we announced results from a Phase 3 trial for HEPLISAV in an older, more difficult-to-immunize population in Asia showing statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B. In December 2006, we announced the results of a Phase 2 trial showing equivalent seroprotection from a shorter two-dose vaccination schedule in subjects 18 to 39 years of age. A U.S.-based Phase 1 trial in patients with end-stage renal disease is ongoing. We have planned additional trials designed to support registration activities. In December 2006, we initiated

a pivotal Phase 3 safety and efficacy trial for HEPLISAV in subjects 11 to 55 years of age in Canada followed by the planned initiation of parallel trial sites in the U.S. and Europe in 2007. Also in 2007, we anticipate initiating a Phase 2 trial in the end-stage renal disease population that would be conducted in Europe and/or Canada.

**Table of Contents**

***TOLAMBA***

TOLAMBA (Amb a 1 ISS Conjugate, or AIC) is an injectable product candidate to treat ragweed allergy. In April 2006, we initiated the Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT. The DARTT study was a 30-center, placebo-controlled study that enrolled 738 ragweed allergic subjects, aged 18 to 55 years. The study randomized subjects into three arms: prior dosing regimen; a higher total dose regimen; and placebo. Subjects received six doses of TOLAMBA over six weeks prior to the start of the 2006 ragweed season. In February 2007, we reported that the analysis of interim one-year data from DARTT indicated that no meaningful ragweed-specific allergic disease was observed in the overall study population, making it impossible to measure the therapeutic effect of TOLAMBA treatment. In all three arms of the study, including the placebo arm, minimal change from baseline was observed in the TNSS. In the placebo and treated groups, the change from baseline TNSS was very low, not clinically significant, and substantially lower than what has been observed in prior trials. Entry criteria for the DARTT study, including a clinical history of ragweed allergy and a confirmatory skin test did not reproducibly select patients with moderate to severe disease. The same enrollment criteria were used in a 313-subject clinical trial of TOLAMBA in ragweed allergic children, the primary endpoint of which was improvement in allergy symptoms following the second (2006) ragweed season. The results of the pediatric trial showed an even lower incidence of ragweed-specific allergic disease in children. Given the low level of disease in the trials' study populations, we believe the planned second and third year follow-up analyses for DARTT and the pediatric trial are unlikely to yield valuable data, and as a result, we have decided to discontinue both studies.

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

Results from a two-year Phase 2 clinical trial of TOLAMBA showed that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores and other efficacy endpoints compared to placebo-treated patients in the trial. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

We are currently in the process of evaluating the feasibility of new trial designs, defining a regulatory path, and projecting the timeline and costs, including partnership opportunities, associated with advancing the TOLAMBA program.

***Symphony Dynamo, Inc.***

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer therapy, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, SDI agreed to invest \$50.0 million to fund the clinical development of these programs and we licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We are primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, representing a 25% premium over the 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. 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. In consideration for the warrant, we received an exclusive purchase option to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. The purchase option exercise price is payable in cash or a combination of cash and shares of our common stock, at our sole

## **Table of Contents**

discretion. We also have an option to purchase either the hepatitis B or hepatitis C program during the first year of the agreement. The program option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the purchase option. If we do not exercise our exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

In cancer, 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. In December 2006, we initiated a Phase 1 dose escalation clinical trial of our cancer product candidate in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. In March 2007, we initiated a Phase 1 trial of our therapy for chronic HBV infection. We anticipate that additional cancer product candidates will advance into clinical trials in solid tumors in 2007, and our hepatitis C therapeutic product candidate is also planned to enter the clinic in 2007.

### ***ISS for Non-Hodgkin's Lymphoma***

We have an ongoing Phase 2 study in non-Hodgkin's lymphoma, or NHL, of ISS in combination with Rituximab<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. Patients treated with the combination therapy showed a prolonged time to progression as compared to patients who were less responsive to the drug and to historical controls. 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.

### ***AstraZeneca Research Collaboration and License Agreement***

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.

### ***Influenza Vaccine***

In the fourth quarter of 2006, we announced preclinical data that show our flu vaccine can improve the immunogenicity of standard flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with standard vaccine enhances the immune response of the standard vaccine, allows reduction of standard vaccine dosage, and provides extra layers of protection that are not strain-dependent. Our flu vaccine is based on our proprietary TLR9 agonist-based ISS technology. The preclinical work was funded in part by a research and development grant for a pandemic flu vaccine from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health.

### ***SUPERVAX***

In April 2006, we completed the acquisition of Rhein Biotech GmbH, which we refer to as Dynavax Europe. As a result, we acquired a hepatitis B vaccine called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection when administered on a two-dose schedule. SUPERVAX was launched



in Argentina in December 2006 and is approved for marketing and sales through a third party partner. We intend to continue registration activities for SUPERVAX as a two-dose vaccine for adolescents for commercialization through partners in select countries outside of North America and Europe.

## **Table of Contents**

### **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, 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***

We recognize revenue from collaborative agreements, the performance of research and development and contract manufacturing services, royalty and license fees and grants. 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.

Revenues from collaboration and research and development service agreements are recognized as work is performed. Any upfront fees or amounts received in advance of performance are recorded as deferred revenue and recognized as earned over the estimated term of the performance obligation. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations and milestones 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. Revenues from license fees and royalty payments are recognized when earned; up-front nonrefundable fees where we have no continuing performance obligations are recognized as revenues when collection is reasonably assured.

Grant 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. In instances where we enter into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, 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.

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. In the normal course of business 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

## **Table of Contents**

to contract and may result in uneven payment flows. 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 at any point in time during the contract, subject to certain 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, 2006, the total unrecognized compensation cost related to non-vested options granted amounted to \$8.1 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.8 years.

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment, including estimating forfeiture rates, stock price volatility and expected option life. 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%. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 6.25 years. Non-executive level employees were found to have similar historical option exercise and termination behavior resulting 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 assist in determining the value of the acquired in-process research and development and certain other intangibles associated with the Rhein Biotech GmbH transaction, we obtained a third party valuation as of the acquisition date. 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 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

## **Table of Contents**

significant estimates and assumptions. We believe the estimated fair value assigned to the in-process research and development and other intangibles 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*.

### ***Valuation 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***

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.

**Table of Contents****Results of Operations*****Revenues***

Revenues consist of amounts earned from collaborations, services, license fees and grants. Collaboration revenue includes revenue recognized under our collaboration agreements with AstraZeneca in 2006 and UCB in 2005 and 2004. Services and license fees include research and development and contract manufacturing services, license fees, royalty payments, and sales of SUPERVAX formulated bulk vaccine to a third party distributor. Grant revenue includes amounts earned under government and private agency grants.

The following is a summary of our revenues for the years ended December 31, 2006, 2005 and 2004 (in thousands):

<b>Results of Operations:</b>	<b>Years Ended December 31,</b>			<b>Increase (Decrease) from</b>		<b>Increase (Decrease) from</b>	
	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2005 to 2006</b>		<b>2004 to 2005</b>	
				<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Revenues:							
Collaboration revenue	\$ 1,557	\$ 12,199	\$ 13,782	\$ (10,642)	(87)%	\$ (1,583)	(11)%
Grant revenue	1,549	2,456	1,030	(907)	(37)%	1,426	138%
Services and license revenue	1,741			1,741			
Total revenues	\$ 4,847	\$ 14,655	\$ 14,812	\$ (9,808)	(67)%	\$ (157)	(1)%

Total revenues were \$4.8 million for the year ended December 31, 2006 as compared with \$14.7 million for the year ended December 31, 2005. Collaboration revenue in 2006 consisted of revenue primarily from AstraZeneca. Services and license revenue includes approximately \$1.2 million from R&D services provided to customers of Dynavax Europe and \$0.1 million in sales of SUPERVAX formulated bulk vaccine to a third party distributor. Grant revenue consists primarily of grants awarded by the National Institute of Allergy and Infectious Diseases.

Collaboration revenue for the year ended December 31, 2005 included accelerated recognition of \$7.0 million in deferred revenue following the end of our collaboration with UCB in March 2005. Grant revenue for the year ended December 31, 2005 included an increase of \$0.5 million associated with our National Institutes of Health (NIH) awards, reflecting an adjustment from the previously utilized minimum cost overhead rate allowable to the final approved indirect cost rate. Total revenues in fiscal 2004 were derived primarily from our collaborative agreement with UCB, which was initiated in the first quarter of 2004.

We anticipate that our revenues will increase in 2007 as compared to 2006 mainly due to research funding under our collaboration with AstraZeneca.

***Research and Development***

Research and development expenses consist of compensation and related personnel costs which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates, and the costs of selling SUPERVAX formulated bulk vaccine. We expense our research and development



costs as they are incurred.

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

<b>Research and Development:</b>	<b>Years Ended December 31,</b>			<b>Increase (Decrease) from 2005 to 2006</b>		<b>Increase (Decrease) from 2004 to 2005</b>	
	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Compensation and related personnel costs	\$ 13,006	\$ 8,563	\$ 6,896	\$ 4,443	52%	\$ 1,667	24%
Outside services	31,042	15,084	12,408	15,958	106%	2,676	22%
Facility costs	4,988	3,673	2,546	1,315	36%	1,127	44%
Non-cash stock-based compensation	1,080	567	1,279	513	90%	(712)	(56)%
<b>Total research and development</b>	<b>\$ 50,116</b>	<b>\$ 27,887</b>	<b>\$ 23,129</b>	<b>\$ 22,229</b>	<b>80%</b>	<b>\$ 4,758</b>	<b>21%</b>

**Table of Contents**

Research and development expenses for the year ended December 31, 2006 increased by \$22.2 million, or 80%, over the same period in 2005. The increase from fiscal 2005 was primarily due to increased clinical trial and clinical material manufacturing costs related to our product candidates TOLAMBA and HEPLISAV and expenses incurred to support SDI programs and Dynavax Europe operations. Outside services during the period also included approximately \$0.1 million of cost associated with SUPERVAX formulated bulk vaccine. Compensation and related personnel costs increased in 2006 resulting from continued organizational growth to further develop our clinical candidates and the impact 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.

Research and development expenses for the year ended December 31, 2005 increased by \$4.8 million, or 21%, from the same period in 2004. The increase from fiscal year 2004 was driven by clinical trial and clinical manufacturing activities related to TOLAMBA and HEPLISAV. During 2005, we incurred costs associated with the second year of the TOLAMBA Phase 2 clinical trial and the initiation of the clinical trial in ragweed allergic children, as well as the HEPLISAV pivotal Phase 3 trial in Asia. Compensation and related personnel costs also increased in 2005 attributed to continued organizational growth. Facility costs increased resulting from a full year of allocated rent and operating costs associated with our new facility entered into in the third quarter of 2004.

We anticipate that our research and development expenses will increase significantly in 2007 as compared to 2006, primarily in connection with the advancement of HEPLISAV and our programs in cancer, hepatitis B and hepatitis C therapies, asthma and flu.

**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 non-cash stock-based compensation.

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

<b>General and Administrative:</b>	<b>Years Ended December 31,</b>			<b>Increase (Decrease) from</b>		<b>Increase (Decrease) from</b>	
	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2005 to 2006</b>		<b>2004 to 2005</b>	
	\$	\$	\$	\$	%	\$	%
Compensation and related personnel costs	\$ 6,264	\$ 4,426	\$ 3,322	\$ 1,838	42%	\$ 1,104	33%
Outside services	4,008	2,372	1,729	1,636	69%	643	37%
Legal costs	1,727	1,117	1,291	610	55%	(174)	(13)%
Facility costs	591	510	743	81	16%	(233)	(31)%
Other	43			43			
Non-cash stock-based compensation	2,203	833	1,458	1,370	164%	(625)	(43)%
Total general and administrative	\$ 14,836	\$ 9,258	\$ 8,543	\$ 5,578	60%	\$ 715	8%

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.

General and administrative expenses for the year ended December 31, 2005 increased by \$0.7 million, or 8%, from the same period in 2004. The increase from fiscal 2004 primarily reflects higher compensation and related benefits associated with overall organizational growth. In addition, outside services, including

**Table of Contents**

administrative, accounting and consulting fees, increased primarily as a result of the review and testing of our internal control systems in compliance with the requirements of the Sarbanes-Oxley Act. These increases were offset by a decrease in stock based compensation expense due to certain options being fully vested by the end of 2004. Legal and patent-related costs during the year ended December 31, 2005 were net of \$0.2 million in reimbursable patent interference costs.

We expect general and administrative expenses to increase modestly in 2007 as compared to 2006, resulting from continued organizational growth and expenses incurred to support the advancement of our clinical development programs and corporate development activities.

**Acquired In-process Research and Development**

Following our April 2006 acquisition of 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.

**Amortization of Intangible Assets**

Intangible assets resulting from our April 2006 acquisition of Rhein consist primarily of manufacturing process, customer relationships, and developed technology. Amortization of intangible assets was \$0.7 million for the year ended December 31, 2006.

**Interest and Other Income, Net**

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 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):

	Years Ended December 31,			Increase (Decrease) from 2005 to 2006		Increase (Decrease) from 2004 to 2005	
	2006	2005	2004	\$	%	\$	%
Interest income, net	\$ 3,088	\$ 1,935	\$ 889	\$ 1,153	60%	\$ 1,046	118%
Other income, net	100			100			
Interest and other income, net	\$ 3,188	\$ 1,935	\$ 889	\$ 1,253	65%	\$ 1,046	118%

Interest and other income, net for the year ended December 31, 2006 increased by \$1.3 million, or 65%, 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. Interest and other income, net for the year ended December 31, 2005 increased by \$1.0 million, or 118%, over the same period in 2004, resulting mainly from the investment of proceeds from our follow-on equity offering in the fourth quarter of 2005.

***Noncontrolling Interest in Symphony Dynamo, Inc.***

Pursuant to the agreements that we entered into with SDI in April 2006, the results of operations of SDI have been included in our consolidated financial statements from the date of formation. Collaboration funding for SDI programs was \$9.7 million for the period from April 18, 2006 through December 31, 2006. Collaboration funding, net of certain administrative expenses incurred and interest income earned by SDI, is reflected in the amount attributed to the noncontrolling interest in SDI.

## **Table of Contents**

### **Recent Accounting Pronouncements**

In July 2006, the FASB released the Final Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease with in a twelve month period. We are required to adopt FIN 48 on January 1, 2007. We are currently evaluating the impact of FIN 48 on our consolidated financial position, results of operations, and cash flows.

### **Liquidity and Capital Resources**

As of December 31, 2006, we had \$72.8 million in cash, cash equivalents and marketable securities and \$13.4 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 for biodefense programs. We have also financed certain of our research and development activities under our agreements with SDI.

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.

On August 31, 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. \$15 million remains available on our equity line of credit.

Cash used in operating activities of \$37.2 million during the year ended December 31, 2006 compared to \$22.9 million for the same period in 2005. 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 operating activities during 2005 increased from 2004 primarily due to the increase in our net loss from operations and the increase in working capital.

Cash used in investing activities of \$20.4 million during the year ended December 31, 2006 compared to \$18.7 million for the same period in 2005. The increase was attributed 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 used in investing activities during 2005 decreased from 2004 resulting mainly from net maturities of marketable securities

during the year.

Cash provided by financing activities of \$62.9 million during the year ended December 31, 2006 compared to \$33.7 million for the same period in 2005. Cash provided by financing activities primarily included the net proceeds from the sale of our common stock in all years presented. Cash provided by

**Table of Contents**

financing activities during 2006 increased from 2005 and 2004 primarily due to \$17.4 million in proceeds from the purchase of the noncontrolling interest in SDI, net of fees.

We currently anticipate that our cash and cash equivalents, marketable securities, investments held and expected to be made in April 2007 by SDI, and our Azimuth equity line of credit 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.

***Contractual Obligations***

The following summarizes our significant contractual obligations as of December 31, 2006 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>Payments Due by Period</b>	
		<b>Less than 1 Year</b>	<b>1-3 Years</b>
Future minimum payments under our operating lease	\$ 5,974	\$ 2,198	\$ 3,776
Total	\$ 5,974	\$ 2,198	\$ 3,776

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 August 2009, 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 \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

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, 2006 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2006 and December 31, 2005. 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 up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

## **Table of Contents**

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2006, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$30 million through 2008. These obligations include services for our TOLAMBA program, which we anticipate could be reduced by as much as \$16 million following the termination of the DARTT and pediatric clinical trials in the first quarter of 2007. 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 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time.

In December 2004, Rhein entered into a joint venture agreement under which it is obligated to perform research and development services up to a maximum of 1.5 million Euro, or approximately \$2.0 million, related to the development of a vaccine for cytomegalovirus. As of December 31, 2006, the remaining obligation was approximately \$0.9 million.

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

We do not have any off-balance sheet arrangements as defined by rules recently 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. 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, 2006 was \$0.1 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

**Table of Contents**

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page No.</b>
<u>Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting</u>	48
<u>Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements</u>	50
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	51
<u>Consolidated Statements of Operations</u>	52
<u>Consolidated Statement of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)</u>	53
<u>Consolidated Statements of Cash Flows</u>	54
<u>Notes to Consolidated Financial Statements</u>	55

**Table of Contents**

**Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting**

To The Board of Directors and Stockholders  
Dynavax Technologies Corporation

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting included in Item 9A., that Dynavax Technologies Corporation maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of Dynavax Technologies Corporation'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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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.

As indicated in the accompanying Management's Annual Report on Internal Controls over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Rhein Biotech GmbH, acquired on April 21, 2006 or Symphony Dynamo, Inc., established on April 18, 2006, both of which are included in the 2006 consolidated financial statements of Dynavax Technologies Corporation. Rhein Biotech GmbH constituted \$9.5 million and \$2.2 million of total assets and net liabilities, respectively, as of December 31, 2006 and \$5.5 million and \$2.1 million of revenues and net operating loss, respectively, for the year then ended. Symphony Dynamo, Inc. constituted \$13.5 million and \$10.3 million of total and net assets, respectively, as of December 31, 2006 and \$9.7 million of net loss for the year then ended. Our audit of internal control over financial reporting of Dynavax Technologies Corporation also did not include an evaluation of the internal control over financial reporting of either Rhein Biotech GmbH or Symphony Dynamo, Inc.

In our opinion, management's assessment that Dynavax Technologies Corporation maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion,

**Table of Contents**

Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2006 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 9, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Francisco, California  
March 9, 2007

**Table of Contents**

**Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements**

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, 2006 and 2005, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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 fiscal 2006 Dynavax Technologies Corporation changed 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, 2006, 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 9, 2007, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Francisco, California

March 9, 2006



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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,154	\$ 8,725
Marketable securities	58,677	66,385
Investments held by Symphony Dynamo, Inc.	13,363	
Restricted cash	408	408
Accounts receivable	2,154	689
Inventory	257	
Prepaid expenses and other current assets	673	1,277
Total current assets	89,686	77,484
Property and equipment, net	5,200	2,197
Goodwill	2,312	
Other intangible assets, net	4,382	
Other assets	1,310	412
Total assets	\$ 102,890	\$ 80,093
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,181	\$ 952
Accrued liabilities	10,742	3,841
Deferred revenues	778	750
Total current liabilities	13,701	5,543
Deferred revenues, noncurrent	10,000	
Other long-term liabilities	117	187
Noncontrolling interest in Symphony Dynamo, Inc.	2,016	
Commitments and contingencies		
Stockholders equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2006 and 2005		
Common stock: \$0.001 par value; 100,000 shares authorized at December 31, 2006 and 2005; 39,715 and 30,482 shares issued and outstanding at December 31, 2006 and 2005, respectively	40	30
Additional paid-in capital	244,787	192,840
Deferred stock compensation		(2,467)

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Accumulated other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities available-for-sale	28	(144)
Cumulative translation adjustment	144	(5)
Accumulated other comprehensive income (loss)	172	(149)
Accumulated deficit	(167,943)	(115,891)
Total stockholders' equity	77,056	74,363
Total liabilities and stockholders' equity	\$ 102,890	\$ 80,093

*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>2006</b>	<b>2005</b>	<b>2004</b>
Revenues:			
Collaboration revenue	\$ 1,557	\$ 12,199	\$ 13,782
Service and license revenue	1,741		
Grant revenue	1,549	2,456	1,030
Total revenues	4,847	14,655	14,812
Operating expenses:			
Research and development	50,116	27,887	23,129
General and administrative	14,836	9,258	8,543
Acquired in-process research and development	4,180		
Amortization of intangible assets	698		
Total operating expenses	69,830	37,145	31,672
Loss from operations	(64,983)	(22,490)	(16,860)
Interest and other income, net	3,188	1,935	889
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(61,795)	(20,555)	(15,971)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	9,743		
Net loss	\$ (52,052)	\$ (20,555)	\$ (15,971)
Basic and diluted net loss per share	\$ (1.61)	\$ (0.79)	\$ (0.75)
Shares used to compute basic and diluted net loss per share	32,339	25,914	21,187

*See accompanying notes.*

Table of Contents

## DYNAVAX TECHNOLOGIES CORPORATION

**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS  
EQUITY  
(NET CAPITAL DEFICIENCY)**

(In thousands, except per share amounts)

	Convertible		Common Stock		Additional	Deferred Stock Compensation	Notes	Accumulated Other	Accumulated Deficit	Stockholders' Equity (Net Capital Deficiency)
	Preferred Stock Shares	Amount	Shares	Par Amount	Paid-In Capital		From Stockholders	Income (Loss)		Capital Deficiency
Shares at December 31, 2003	39,514	\$ 83,635	1,884	\$ 2	\$ 12,762	\$ (4,677)	\$ (654)	\$	\$ (79,365)	\$ (71,192)
Issuance of common stock upon initial public offering			6,900	7	46,448					46,455
Conversion of convertible preferred stock upon public offering	(39,514)	(83,635)	13,712	14	83,621					83,625
Issuance of warrant shares in DYNAVAX Asia upon public offering			2,111	2	14,731					14,733
Exercise of stock options			7		16					
Issuance of common stock under Employee Stock Purchase Plan			13		70					
Interest accrued on notes receivable from stockholders							(37)			
Payment of notes receivable from stockholders							272			
Conversion of convertible preferred stock upon redemption					1,426	(1,426)				
Conversion of convertible preferred stock upon redemption						2,737				2,737
Comprehensive loss: Change in unrealized gain on marketable								(102)		(102)

ities									
ross								(15,971)	(15,971)
prehensive loss									(16,000)
ces at									
ber 31, 2004	24,627	25	159,074	(3,366)	(419)	(102)		(95,336)	59,000
ce of common									
upon public									
ng	5,720	5	33,132						33,132
ise of stock									
as	113		19						
ce of common									
under									
oyee Stock									
ase Plan	22		114						
st accrued on									
receivable from									
holders							(16)		
ment of notes									
able from									
holders							435		
red stock									
ensation			501	(501)					
tization of									
red stock									
ensation							1,400		1,400
prehensive loss:									
ge in unrealized									
n marketable									
ities							(42)		
lative									
ation adjustment							(5)		
ross								(20,555)	(20,555)
prehensive loss									(20,555)
ces at									
ber 31, 2005	30,482	30	192,840	(2,467)		(149)		(115,891)	74,000
ce of common									
upon equity									
ngs	8,794	9	44,032						44,032
ise of stock									
as	412	1	1,339						1,339
ce of common									
under									
oyee Stock									
ase Plan	27		114						
ce of warrants			5,646						5,646
junction with									
hony Dynamo,									

Transaction									
Compensation									
se				3,283					3
Classification of									
red stock									
Compensation balance									
Adoption of									
123R				(2,467)	2,467				
Comprehensive loss:									
Change in unrealized									
on marketable									
ties							172		
Relative									
ation adjustment							149		
Loss								(52,052)	(52
Comprehensive loss									(51
ces at									
ember 31, 2006	\$	39,715	\$ 40	\$ 244,787	\$	\$	\$ 172	\$ (167,943)	\$ 77

*See accompanying notes.*

**Table of Contents**

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

(In thousands)

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Operating activities</b>			
Net loss	\$ (52,052)	\$ (20,555)	\$ (15,971)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,130	759	536
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	(9,743)		
Acquired in-process research and development	4,180		
Amortization of intangible assets	698		
(Gain) loss on disposal of property and equipment	(36)		18
Accretion and amortization on marketable securities	(296)	973	361
Realized loss (gain) on investments	23	(1)	
Interest accrued on notes receivable from stockholders		(16)	(37)
Stock-based compensation expense	3,283	1,400	2,737
Changes in operating assets and liabilities:			
Accounts receivable	(976)	2,442	(2,911)
Prepaid expenses and other current assets	604	119	26
Inventory	(257)		
Other assets	(513)	(10)	(384)
Accounts payable	1,006	(439)	(19)
Accrued liabilities	5,847	(530)	1,312
Deferred revenues	9,862	(7,000)	7,000
Net cash used in operating activities	(37,240)	(22,858)	(7,332)
<b>Investing activities</b>			
Purchases of investments held by Symphony Dynamo, Inc.	(13,363)		
Cash paid for acquisition, net of cash acquired	(14,045)		
Purchases of marketable securities	(65,842)	(84,014)	(49,637)
Maturities and sales of marketable securities	73,995	65,869	5,549
Purchases of property and equipment	(1,125)	(562)	(1,863)
Net cash used in investing activities	(20,380)	(18,707)	(45,951)
<b>Financing activities</b>			
Proceeds from issuance of common stock, net of issuance costs	44,041	33,137	46,455
Proceeds from purchase of noncontrolling interest by shareholders in Symphony Dynamo, Inc., net of fees	17,405		
Exercise of stock options	1,340	19	16
Proceeds from employee stock purchase plan	114	114	70
Repayment of notes receivable from stockholders		435	272

Restricted cash			(408)
Net cash provided by financing activities	62,900	33,705	46,405
Effect of exchange rate on cash and cash equivalents	149	(5)	
Net increase (decrease) in cash and cash equivalents	5,429	(7,865)	(6,878)
Cash and cash equivalents at beginning of year	8,725	16,590	23,468
Cash and cash equivalents at end of year	\$ 14,154	\$ 8,725	\$ 16,590

**Supplemental disclosure of non-cash investing and financing activities**

Warrants issued in conjunction with the Symphony Dynamo, Inc. transaction	\$ 5,646	\$	\$
Disposal of fully depreciated property and equipment	\$ 395	\$ 60	\$
Change in unrealized gain (loss) on marketable securities	\$ 172	\$ (42)	\$ (102)
Lease incentive	\$	\$	\$ 350
Exercise of stock options	\$	\$ 200	\$
Repurchase of common stock for exercise of stock options	\$	\$ (200)	\$
Conversion of preferred stock upon initial public offering	\$	\$	\$ 83,635
Conversion of ordinary shares in Dynavax Asia upon initial public offering	\$	\$	\$ 14,733
Interest accrued on notes receivable	\$	\$	\$ 37

*See accompanying notes.*



**Table of Contents**

**DYNAVAX TECHNOLOGIES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization**

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. We originally incorporated in California on August 29, 1996 and reincorporated in Delaware on March 26, 2001.

**Subsidiaries**

In October 2003, we formed Dynavax Asia Pte. Ltd. (Dynavax Asia), a wholly-owned subsidiary in Singapore. Our wholly-owned subsidiary in Japan formed in December 2004, Ryden Therapeutics KK, was liquidated in the fourth quarter of 2006. In April 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, a wholly-owned subsidiary in Düsseldorf, Germany.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries as well as a variable interest entity, Symphony Dynamo, Inc., or SDI, for which we are the primary beneficiary as defined by Financial Accounting Standards Board, or FASB, 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.

As discussed below in Note 2, we adopted Statement of Financial Accounting Standards No. 123R, Share-Based Compensation (FAS 123R) on January 1, 2006 using the modified prospective transition method. Accordingly, our net loss for the year ended December 31, 2006 includes approximately \$2.0 million in stock-based compensation expense for our employee stock option and employee stock purchase plans that we recorded as a result of adopting FAS 123R. Because we elected to use the modified prospective transition method, results for prior periods have not been restated.

**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.

**Table of Contents**

**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.

Investments held by SDI consist of investments in money market funds. As of December 31, 2006, we had investments held by SDI of \$13.4 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 although the stated maturity may be one year or more beyond 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, protection of proprietary technology, compliance with government

## **Table of Contents**

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

### **Inventory**

Included in inventory 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**

We identify and record impairment losses on long-lived assets when events and circumstances indicate that the carrying value may not be recoverable. Recoverability is measured by comparison of the assets' carrying amounts to the future net undiscounted cash flows the assets are expected to generate. If these assets are considered impaired, the impairment recognized is measured by the amount by which the carrying value of the assets exceeds the projected discounted future net cash flows associated with the assets. None of these events or circumstances has occurred with respect to our long-lived assets, which consist mainly of lab equipment.

### **Revenue Recognition**

We recognize revenue from collaborative agreements, the performance of research and development and contract manufacturing services, royalty and license fees and grants. 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.

Revenues from collaboration and research and development service agreements are recognized as work is performed. Any upfront fees or amounts received in advance of performance are recorded as deferred revenue and recognized as earned over the estimated term of the performance obligation. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations and milestones 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. Revenues from license fees and royalty payments are recognized when earned; up-front nonrefundable fees where we have no continuing performance obligations are recognized as revenues when collection is reasonably assured.

Grant 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. In instances where we enter into agreements with third parties for clinical trials, manufacturing and

## **Table of Contents**

process development, research and other consulting activities, 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.

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. In the normal course of business 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. 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 at any point in time during the contract, subject to certain 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 assist in determining the value of the acquired in-process research and development, or in-process R&D, and certain other intangibles associated with the Rhein Biotech GmbH transaction discussed in Note 6, we obtained a third party valuation as of the acquisition date. 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 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 and other intangibles 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



## **Table of Contents**

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 7.

## **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.

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment, including estimating forfeiture rates, stock price volatility and expected option life. 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%. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions including the expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 6.25 years. Non-executive level employees were found to have similar historical option exercise and termination behavior resulting 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 SFAS 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

**Table of Contents**

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.

**Recent Accounting Pronouncements**

In July 2006, the FASB released the final Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease with in a twelve month period. We are required to adopt FIN 48 on January 1, 2007. We are currently evaluating the impact of FIN 48 on our consolidated financial position, results of operations, and cash flows.

**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, 2006 and 2005 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<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
<b>December 31, 2005:</b>				
Certificates of deposit and money market funds	\$ 9,005	\$	\$	\$ 9,005
Corporate debt securities	66,529		(144)	66,385
Total	\$ 75,534	\$	\$ (144)	\$ 75,390

There were no realized gains from the sale of marketable securities for the years ended December 31, 2006 and 2005. Realized losses from the sale of marketable securities were \$23,000 in 2006 and zero in 2005. As of December 31, 2006 and 2005, 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, 2006, our marketable securities had the following maturities (in thousands):

Maturities:	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 85,445	\$ 85,473

Total	\$	85,445	\$	85,473
-------	----	--------	----	--------

#### 4. Inventory

Inventories as of December 31, 2006 consist of the following (in thousands):

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

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

Property and equipment as of December 31, 2006 and 2005 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Laboratory equipment	\$ 9,984	\$ 2,638
Computer equipment	1,156	797
Furniture and fixtures	1,396	755
Leasehold improvements	1,968	1,257
	14,504	5,447
Less accumulated depreciation and amortization	(9,304)	(3,250)
Total	\$ 5,200	\$ 2,197

Depreciation and amortization expense on property and equipment was \$1.2 million, \$0.8 million and \$0.5 million for the years ended December 31, 2006, 2005, and 2004, 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, 2006 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<sup>™</sup> 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

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 utilized a third party valuation expert to assess the fair value of the identifiable intangible assets acquired, as well as in-process research and development. The purchase price was allocated using information available at the time of acquisition. We may adjust the preliminary purchase price relating to goodwill, intangible assets and in-process R&D after obtaining more

**Table of Contents**

information regarding, among other things, asset valuations, liabilities assumed and revisions of preliminary estimates. The excess of purchase price over the aggregate fair values was recorded as goodwill.

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

**Allocation of purchase price:**

Cash and cash equivalents	\$ 513
Accounts receivable	489
Other current assets	385
Property, plant and equipment	3,092
Goodwill	2,312
Intangible assets	5,080
In-process research and development	4,180
Accounts payable	(273)
Deferred revenue	(166)
Other current liabilities	(1,054)
 Total purchase price	 \$ 14,558

Intangible assets consist primarily of manufacturing process, customer relationships, and developed technology. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. The developed technology derives from a licensed hepatitis B vaccine product. 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 acquired (in thousands, except years):

	<b>Estimated Useful Life (In years)</b>	<b>Amount</b>
<b>Intangible Assets:</b>		
Manufacturing process	5	\$ 3,670
Customer relationships	5	1,230
Developed technology	7	180
 Total		 \$ 5,080

	<b>Gross</b>	<b>Accumulated Amortization</b>	<b>Net</b>
<b>December 31, 2006:</b>			
Manufacturing process	\$ 3,670	\$ 509	\$ 3,161
Customer relationships	1,230	171	1,059

Developed technology	180	18	162
Total	\$ 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>	
2007	\$ 1,006
2008	1,006
2009	1,006
2010	1,005
Thereafter	359
<b>Total</b>	<b>\$ 4,382</b>

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. Total in-process R&D expense was \$4.2 million for the year ended December 31, 2006.

The unaudited financial information in the table below summarizes the combined results of operations of Dynavax and Rhein, on a pro forma basis, as though the companies had been combined as of January 1, 2006 and 2005. The pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of each of the periods presented. The pro forma financial information for the year ended December 31, 2006 includes a charge for the write off of in-process R&D. The pro forma financial information for all periods presented also includes the purchase accounting adjustments on Rhein's revenue, adjustments to depreciation on acquired property and equipment, and amortization charges from acquired intangible assets.

The following table summarizes the unaudited pro forma financial information (in thousands, except per share amounts):

	<b>Years Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
Revenues	\$ 5,533	\$ 17,844
Net loss	\$ (54,340)	\$ (25,256)
Basic and diluted earnings per share	\$ (1.68)	\$ (0.97)

**7. Symphony Dynamo, Inc.**

On April 18, 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, Symphony Dynamo, Inc., or SDI, agreed to invest \$50.0 million to fund the clinical development of these programs and we licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We are primarily responsible for the development of these programs.

In accordance with FIN 46R, we have determined that SDI is a variable interest entity for which we are the primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements as of December 31, 2006 and for the period from April 18, 2006 through December 31, 2006. Accordingly, the investments held by SDI and noncontrolling interest in SDI in the consolidated balance sheet include the initial \$20.0 million of funding, less funds spent to date on the development of the programs. The noncontrolling interest in SDI, which will continue to be reduced by SDI's losses, was also reduced initially by (i) the structuring fee and other closing costs of \$2.6 million, and (ii) the value assigned to the warrants issued to Holdings upon closing of \$5.6 million.

**Table of Contents**

Collaboration funding for SDI programs was \$9.7 million for the period from April 18, 2006 through December 31, 2006. Collaboration funding, net of certain administrative expenses incurred and interest income earned by SDI, is reflected in the amount attributed to the noncontrolling interest in SDI.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of common stock 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 under certain circumstances. 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, which was recorded as a reduction in the noncontrolling interest in SDI and an increase in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option, or the Purchase Option, to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. 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 have an option to purchase either the hepatitis B or hepatitis C program, or the Program Option, during the first year of the agreement. The Program Option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If we do not exercise our exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

**8. Current Accrued Liabilities**

Current accrued liabilities as of December 31, 2006 and 2005 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Payroll and related expenses	\$ 1,598	\$ 1,735
Legal expenses	732	273
Third party scientific research expense	6,668	1,354
Other accrued liabilities	1,744	479
Total	\$ 10,742	\$ 3,841

**9. 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 August 2009, respectively. The Berkeley Lease can be terminated in September 2009 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of December 31, 2006 and December 31, 2005. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2009. Total net rent

expense related to our operating leases for the years ended December 31, 2006, 2005 and 2004, was \$1.8 million, \$1.4 million and \$1.4 million, respectively. Deferred rent was \$0.2 million as of December 31, 2006.

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 \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

**Table of Contents**

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2006, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2007	\$ 2,198
2008	2,250
2009	1,526
 Total	 \$ 5,974

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, 2006 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2006 and December 31, 2005. 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 up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2006, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$30 million through 2008. These obligations include services for our TOLAMBA program, which we anticipate could be reduced by as much as \$16 million following the termination of the DARTT and pediatric clinical trials in the first quarter of 2007. 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 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time.

In December 2004, Rhein entered into a joint venture agreement under which it is obligated to perform research and development services up to a maximum of 1.5 million Euro, or approximately \$2.0 million, related to the development of a vaccine for cytomegalovirus. As of December 31, 2006, the remaining obligation was approximately \$0.9 million.

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

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

**Table of Contents**

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 \$0.8 million for the year ended December 31, 2006. As of December 31, 2006, we recorded deferred revenue of \$10.7 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 2005 and 2006 to fund research and development of new treatment approaches for lupus. We recognized revenue associated with the lupus grant of approximately \$0.2 million in each of the years ended December 31, 2006 and 2005.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development of certain biodefense programs. Certain of these grants extend through July 2007. Revenue associated with these grants is recognized as the related expenses are incurred. For years ended December 31, 2006, 2005 and 2004, we recognized revenue of approximately \$1.3 million, \$2.2 million and \$1.0 million, respectively.

**11. 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 potentially dilutive 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 potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

**Table of Contents**

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Historical (in thousands, except per share amounts):</b>			
Numerator:			
Net loss	\$ (52,052)	\$ (20,555)	\$ (15,971)
Denominator:			
Weighted-average common shares outstanding	32,340	25,915	21,200
Less: Weighted-average unvested common shares subject to repurchase	(1)	(1)	(13)
Denominator for basic and diluted net loss per share	32,339	25,914	21,187
Basic and diluted net loss per share	\$ (1.61)	\$ (0.79)	\$ (0.75)
<b>Historical outstanding dilutive securities not included in diluted net loss per share calculation (in thousands):</b>			
Options to purchase common stock	3,421	2,599	1,828
Warrants	2,084	84	84
	5,505	2,683	1,912

**12. Stockholders Equity**

In January 2004, the Board of Directors and stockholders approved the filing of an amended and restated certificate of incorporation upon completion of our initial public offering. The amendment increased our authorized common stock to 100,000,000 shares and decreased authorized preferred stock to 5,000,000 shares.

In February 2004, we sold a total of 6,900,000 shares of common stock in an underwritten initial public offering, raising net proceeds of approximately \$46.5 million. 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.

**Warrants**

In August 2002, in connection with the closing of a preferred stock financing, we issued a warrant to our placement agent. The warrant for 84,411 shares of common stock is exercisable at a price of \$6.18 per share from the date of the grant for five years and remained outstanding at December 31, 2006.

In April 2006, we issued a five-year warrant to Symphony Dynamo Holdings LLC to purchase 2,000,000 shares of common stock 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 under certain circumstances. 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, which has been recorded as a reduction in



the noncontrolling interest in SDI and an increase in additional paid in capital.

### **Stock Option Plans**

As of December 31, 2006, 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.

**Table of Contents**

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 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.

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, 2006, 4,300,000 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.

**Table of Contents**

Activity under our stock option plans is set forth below:

	<b>Options Available for Grant</b>	<b>Number of Options Outstanding</b>	<b>Weighted-Average Price Per Share</b>
Balance at December 31, 2003	345,060	1,333,981	\$ 2.45
Options authorized	3,500,000		
Options granted	(514,165)	514,165	\$ 5.06
Options exercised		(7,751)	\$ 2.34
Options canceled	12,081	(12,081)	\$ 3.81
Shares repurchased			
Balance at December 31, 2004	3,342,976	1,828,314	\$ 3.17
Options authorized	400,000		
Options granted	(935,550)	935,550	\$ 6.52
Options exercised		(140,825)	\$ 1.55
Options canceled	24,242	(24,242)	\$ 6.95
Shares repurchased	27,817		\$ 7.19
Shares retired	(27,817)		\$ 7.19
Balance at December 31, 2005	2,831,668	2,598,797	\$ 4.43
Options authorized	400,000		
Options granted	(2,080,780)	2,080,780	\$ 5.79
Options exercised		(411,985)	\$ 3.25
Options forfeited	765,992	(765,992)	\$ 5.07
Shares expired	80,261	(80,261)	\$ 4.28
Balance at December 31, 2006	1,997,141	3,421,339	\$ 5.26

**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, 2006, 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 61,774 shares of our common stock under the Purchase Plan. At December 31, 2006, 434,226 shares of our common stock remained available for future purchases.

## **Stock-Based Compensation**

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 years ended 2004 and 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>Years Ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss, as reported	\$ (20,555)	\$ (15,971)
Add: Stock-based employee compensation expense included in net loss	1,410	2,170
Less: Stock-based employee compensation expense determined under the fair value based method	(2,785)	(2,816)
Net loss, pro forma	\$ (21,930)	\$ (16,617)
Net loss per share:		
Basic and diluted, as reported	\$ (0.79)	\$ (0.75)
Basic and diluted, pro forma	\$ (0.84)	\$ (0.78)

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous service). The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

	<b>Employee Stock Options</b>			<b>Employee Stock Purchase Plan</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
Weighted-average fair value	\$ 4.04	\$ 3.68	\$ 5.04	\$ 2.28	\$ 3.03	\$ 7.50
Risk-free interest rate	4.7%	3.7%	2.9%	4.9%	2.9%	2.0%
Expected life (in years)	5.6	4	4	1.2	1.2	0.5
Volatility	0.8	0.7	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.

**Table of Contents**

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Employees and directors stock-based compensation expense	\$ 3,153	\$ 1,410	\$ 2,170
Non-employees stock-based compensation expense	130	(10)	567
<b>Total</b>	<b>\$ 3,283</b>	<b>\$ 1,400</b>	<b>\$ 2,737</b>

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized for the year ended December 31, 2006 was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of December 31, 2006, the total unrecognized compensation cost related to non-vested options granted amounted to \$8.1 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.8 years.

Total options exercised during the years ended December 31, 2006, 2005 and 2004 were 411,985, 140,825 and 7,751, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2006, 2005 and 2004 was approximately \$1.3 million, \$0.8 million and \$33,000, respectively. No income tax benefits have been realized by us in 2006, 2005 and 2004, 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, 2006:

	<b>Number of</b>	<b>Weighted-Average</b>	<b>Weighted-Average</b>	<b>Aggregate</b>
	<b>Shares</b>	<b>Exercise</b>	<b>Remaining</b>	<b>Intrinsic</b>
		<b>Price</b>	<b>Contractual</b>	<b>Value</b>
		<b>Per Share</b>	<b>Term</b>	<b>(In</b>
			<b>(In years)</b>	<b>thousands)</b>
Outstanding options (vested and expected to vest)	3,024,087	\$ 5.15	8.1	\$ 12,236
Options exercisable	1,177,287	\$ 4.14	6.7	\$ 5,965

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, 2005:

	<b>Number of</b>	<b>Weighted-Average</b>	<b>Weighted-Average</b>	<b>Aggregate</b>
	<b>Shares</b>	<b>Exercise</b>	<b>Remaining</b>	<b>Intrinsic</b>
		<b>Price</b>	<b>Contractual</b>	<b>Value</b>
		<b>Per Share</b>	<b>Term</b>	<b>(In</b>
			<b>(In years)</b>	<b>thousands)</b>

Outstanding options (vested and expected to vest)	2,598,797	\$	4.43	8.1	\$	2,300
Options exercisable	1,029,309	\$	3.43	7.3	\$	1,432

### 13. 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.



**Table of Contents****14. 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>2006</b>	<b>2005</b>	<b>2004</b>
U.S.	\$ (59,862)	\$ (12,331)	\$ (10,216)
Non U.S.	(1,933)	(8,224)	(5,755)
Total	\$ (61,795)	\$ (20,555)	\$ (15,971)

No income tax expense was recorded for the years ended December 31, 2006, 2005 and 2004 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>2006</b>	<b>2005</b>	<b>2004</b>
Income tax benefit at federal statutory rate	\$ (21,045)	\$ (6,989)	\$ (5,430)
State tax	(3,852)	(1,137)	(758)
Unbenefited foreign losses	(269)	4,752	
Tax credits	(3,088)	(502)	(282)
Deferred compensation charges	(534)	342	931
In-process research and development	1,421		
Change in valuation allowance before impact of purchase accounting for Rhein acquisition	27,391	2,872	5,185
Other	(24)	662	354
	\$	\$	\$

Deferred tax assets and liabilities as of December 31, 2006 and 2005 consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Deferred tax assets:</b>		
Net operating loss carry forwards	\$ 44,278	\$ 24,312
Research tax credit carry forwards	5,871	2,093
Accruals and reserves	1,697	416
Capitalized research costs	18,582	11,012
Other	277	
	70,705	37,833

Less valuation allowance	(68,960)	(37,745)
Total deferred tax assets	\$ 1,745	\$ 88
<b>Deferred tax liabilities:</b>		
Other		(88)
Acquired intangible assets	(1,745)	
Total deferred tax liabilities	\$ (1,745)	\$ (88)
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

**Table of Contents**

assets at December 31, 2006 and 2005. The valuation allowance increased by \$31.2 million, \$2.9 million and \$5.2 million during the years ended December 31, 2006, 2005 and 2004, respectively.

Approximately \$0.3 million of the valuation allowance for deferred tax assets relates to benefits of stock option deductions that, when recognized, will be allocated directly to additional paid in capital.

A provision has not been made at December 31, 2006, for U.S. or additional foreign withholding taxes on undistributed earnings of foreign subsidiaries because it is the present intention of management to reinvest the undistributed earnings indefinitely in foreign operations. Currently there are no undistributed earnings in the foreign subsidiary as it has current and cumulative losses and thus no deferred tax liability would be necessary.

As of December 31, 2006, we had federal net operating loss carryforwards of approximately \$94.9 million and federal research and development tax credits of approximately \$3.5 million, which expire in the years 2011 through 2026. Of these net operating losses, approximately \$9.7 million are attributable to Symphony Dynamo, Inc., which expire in 2026.

As of December 31, 2006, we had net operating loss carryforwards for California state income tax purposes of approximately \$91.2 million, which expire in the years 2012 through 2016, and California state research and development tax credits of approximately \$3.6 million which do not expire.

As of December 31, 2006, we had net operating loss carryforwards for foreign income tax purposes of approximately \$14.5 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.

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

	Year Ended December 31, 2006				Year Ended December 31, 2005			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 288	\$ 529	\$ 1,592	\$ 2,438	\$ 12,698	\$ 953	\$ 404	\$ 600
Net income (loss)(1)(3)	\$ (8,172)	\$ (15,273)	\$ (12,152)	\$ (16,455)	\$ 5,070	\$ (8,579)	\$ (8,284)	\$ (8,762)
Basic net earnings (loss) per share(1)	\$ (0.27)	\$ (0.50)	\$ (0.40)	\$ (0.44)	\$ 0.21	\$ (0.35)	\$ (0.33)	\$ (0.30)
Diluted net earnings (loss) per share(1)	\$ (0.27)	\$ (0.50)	\$ (0.40)	\$ (0.44)	\$ 0.20	\$ (0.35)	\$ (0.33)	\$ (0.30)
Weighted-average shares used in computing basic net loss per share(2)	30,487	30,560	30,605	37,645	24,722	24,745	24,751	29,398
Weighted-average shares used in	30,487	30,560	30,605	37,645	25,023	24,745	24,751	29,398

computing diluted  
net loss per  
share(2)

- (1) Net income and earnings per share for the first quarter of 2005 primarily reflect the financial impact resulting from the termination of our collaboration with UCB Farchim, S.A. that occurred in March 2005 as discussed in Note 10.
- (2) The weighted-average shares increased for fourth quarters of 2005 and 2006 due to the follow on equity offerings that occurred in those periods.
- (3) Our net loss for all quarters in fiscal 2006 includes 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.

**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, 2006.

Management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Rhein Biotech GmbH, acquired on April 21, 2006 or Symphony Dynamo, Inc., established on April 18, 2006, both of which are included in the 2006 consolidated financial statements of Dynavax Technologies Corporation. Rhein Biotech GmbH constituted \$9.5 million and \$2.2 million of total assets and net liabilities, respectively, as of December 31, 2006 and \$5.5 million and \$2.1 million of revenues and net operating loss, respectively, for the year then ended. Symphony Dynamo, Inc. constituted \$13.5 million and \$10.3 million of total and net assets, respectively, as of December 31, 2006 and \$9.7 million of net loss for the year then ended.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in this Annual Report on Form 10-K.

**(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 2007 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, 2006.

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**

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-K

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statement of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

75

---



**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.
10.19(2)	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(3)	Summary of Düsseldorf Lease Agreement as of August 14, 1990, as amended.
10.21(3)	Definitive Commercial Agreement, dated April 21, 2006, among Dynavax Technologies Corporation, Rhein Biotech NV and Rhein Biotech GmbH.
10.22(3)	Exclusive License Agreement, dated April 21, 2006, between Green Cross Vaccine Corp. and Rhein Biotech GmbH.
10.23(3)	Share Sale and Purchase Agreement, dated March 27, 2006, between Dynavax Technologies Corporation and Rhein Biotech N.V.
10.24(3)	License and Supply Agreement, dated February 28, 2002, between Corixa Corporation and Rhein Biotech N.V.
10.25(3)	Purchase Option Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.26(3)	Registration Rights Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.27(3)	Warrant Purchase Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.28(3)	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(3)	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(4)	Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and Dynavax Technologies Corporation.
21.1	List of Subsidiaries.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

(2) 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.

(3) 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.

(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 September 30, 2006, 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 16, 2007

By: /s/ Deborah A. Smeltzer

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

Date: March 16, 2007

By: /s/ Timothy G. Henn

Timothy G. Henn  
 Vice President, Finance and Administration and  
 Chief Accounting Officer  
 (Principal Accounting Officer)

Date: March 16, 2007

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Dino Dina, M.D. Dino Dina, M.D.	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 16, 2007
/s/ Deborah A. Smeltzer Deborah A. Smeltzer	Vice President, Operations and Chief Financial Officer <i>(Principal Financial Officer)</i>	March 16, 2007
/s/ Timothy G. Henn Timothy G. Henn	Vice President, Finance & Administration and Chief Accounting Officer <i>(Principal Accounting Officer)</i>	March 16, 2007
/s/ Arnold Oronsky, Ph.D.*	Chairman of the Board	March 16, 2007

Arnold Oronsky, Ph.D.\*

77

---

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Nancy L. Buc*	Director	March 16, 2007
Nancy L. Buc*		
/s/ Dennis Carson, M.D.*	Director	March 16, 2007
Dennis Carson, M.D.*		
/s/ Denise M. Gilbert, Ph.D.*	Director	March 16, 2007
Denise M. Gilbert, Ph.D.*		
/s/ David M. Lawrence, M.D.*	Director	March 16, 2007
David M. Lawrence, M.D.*		
/s/ Peggy V. Phillips*	Director	March 16, 2007
Peggy V. Phillips*		
/s/ Stanley A. Plotkin, M.D.*	Director	March 16, 2007
Stanley A. Plotkin, M.D.*		
*By: /s/ Deborah A. Smeltzer Deborah A. Smeltzer Attorney-in-Fact		