

DYNAVAX TECHNOLOGIES CORP

Form 10-K/A

August 04, 2006

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

**Form 10-K/A  
Amendment No. 1**

(Mark One)

**R ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2005**

**or**

**£ 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:

None

Name of Each Exchange on Which Registered:

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.  R

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, 2005 as reported on the Nasdaq National Market, was approximately \$96,686,827. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 31, 2006, the registrant had outstanding 30,493,501 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE:** Not applicable.

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**EXPLANATORY NOTE**

The purpose of this Amendment No. 1 to our Form 10-K is to correct Exhibits 31.1 and 31.2, which contained inadvertent omissions of a portion of paragraph 4 at the time they were filed with the original Form 10-K on March 16, 2006. No other items of the original Form 10-K are being amended.

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**FORWARD-LOOKING STATEMENTS**

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

*Actual results may vary materially from those in such 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. Investors and security holders may obtain a free copy of the Annual Report on Form 10-K and other documents filed by Dynavax with the Securities and Exchange Commission (SEC) at the SEC's website at <http://www.sec.gov>. Free copies of the Annual Report on Form 10-K and other documents filed by Dynavax with the SEC may also be obtained from Dynavax by directing a request to Dynavax, Attention: Jane M. Green, Ph.D., Vice President, Corporate Communications, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.*

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Dynavax Technologies Corporation (the Company) discovers, develops and intends to commercialize innovative products to treat and prevent allergies, infectious diseases and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences that we believe enhance the ability of the immune system to fight disease and control chronic inflammation. The most advanced clinical programs in Dynavax's ISS-based pipeline are a ragweed allergy immunotherapeutic and a hepatitis B vaccine.

We have developed a novel injectable product candidate to treat ragweed allergy that we call TOLAMBA<sup>™</sup> (formerly, Amb a 1 ISS Conjugate or AIC). In early 2006, we announced results from a two-year Phase II/III clinical trial of TOLAMBA showing 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 compared to placebo-treated patients in the second year of the trial. The treatment effect was achieved on top of a background of antihistamine and decongestant use. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

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The Company has recently discussed the TOLAMBA program with the U.S. Food & Drug Administration (FDA). The Company has decided to conduct an additional major safety and efficacy trial with the goal of determining whether a more intensive, single-course dosing regimen can elicit an even greater treatment effect than prior regimens. This trial is anticipated to start by the beginning of the second quarter 2006 to take advantage of the 2006 ragweed season. We plan to conduct the trial as a multi-center, well-controlled study and evaluate the results after both the 2006 and 2007 ragweed seasons. The trial broadens the TOLAMBA clinical program and is designed to complement data derived from the Company's recently completed Phase II/ III clinical trial and its ongoing trial in ragweed allergic children initiated in 2005. The Company's goal is to discuss the pathway to registration with the FDA following receipt of results from the first year of this trial.

We have developed a product candidate for hepatitis B prophylaxis called HEPLISAV<sup>tm</sup>. A Phase II/ III trial in subjects who are more difficult to immunize with conventional vaccines conducted in Singapore has been completed. 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. In June 2005, we initiated a pivotal Phase III trial in the older, more difficult to immunize population in Asia. We are in the process of planning additional trials designed to support registration activities. We believe that strategic opportunities for HEPLISAV exist in key global markets. Our initial commercialization strategies will likely target these markets and focus on high-value, underserved populations. These populations include pre-hemodialysis patients, HIV and Hepatitis C Virus (HCV) positive patients, other populations with compromised immune systems as well as professionals in healthcare and law enforcement for whom achieving seroprotection quickly is critical. In October 2005, we announced the initiation of a U.S.-based Phase I clinical trial of HEPLISAV in patients with end-stage renal failure (pre-hemodialysis).

We have an inhaled therapeutic product candidate for treatment of asthma, which has completed a Phase IIa trial in Canada. We are performing additional preclinical work to optimize the route of administration and regimen for the asthma clinical program and have postponed additional clinical trials in asthma.

We are evaluating the potential of ISS to enhance the effect of monoclonal antibodies in cancer therapies. We have conducted an open-label Phase I, dose-escalation trial of ISS in combination with Rituxan<sup>®</sup> (rituximab) in 20 patients with Non-Hodgkin's lymphoma (NHL). Results of this study showed dose dependent pharmacological activity without significant toxicity. A follow-up Phase II trial of ISS with Rituxan in NHL is currently underway in 30 patients with histologically confirmed CD20+, B-cell follicular NHL who have received at least one previous treatment regimen for lymphoma. The primary objective is to assess the proportion of patients who are alive and without disease progression one year after initiating Rituxan therapy. Mechanistic studies will be performed to characterize the enhancement of antitumor activity by ISS.

We have preclinical programs focused on other allergies, chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies.

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**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 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



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

### **ISS and the Immune System**

Our principal product development efforts are based on a technology that uses short synthetic DNA molecules called ISS that stimulate a Th1 immune response while suppressing Th2 immune responses. ISS contain specialized sequences that activate the innate immune system. ISS are recognized by a specialized subset of dendritic cells containing a unique receptor called Toll-Like Receptor 9, or TLR-9. The interaction of TLR-9 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 TLR-9 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, providing long-term suppression of allergic responses.

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

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

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### **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 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 novel 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 novel 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**

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 and asthma. To date, we have administered 1018 ISS to more than 1,000 people without observing any serious, drug-related, adverse events. We have demonstrated the clinical benefit of TOLAMBA and our hepatitis B vaccine, which are both 1018 ISS-based product candidates, in Phase II/ III clinical trials. Our principal programs are Seasonal Allergy Immunotherapy, Hepatitis B Products and Chronic Inflammation, as described below.

### **Seasonal Allergy Immunotherapy**

#### **Ragweed Allergy**

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

Our lead anti-allergy product, 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 convenient 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, we have generated a substantial amount of clinical data on TOLAMBA. TOLAMBA has been tested in fourteen clinical trials in the U.S., France and Canada, and more than 4,700 TOLAMBA injections have been administered to more than 650 patients. In these trials, TOLAMBA was shown to be safe and well tolerated, to provide measurable improvements in allergy

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symptoms and to reduce medication use. We have completed a two-year multi-site Phase II/ III trial in the U.S. to evaluate the efficacy of TOLAMBA. The trial originally enrolled 462 eligible patients. Prior to the 2004 ragweed season, patients received a six-week regimen of either placebo or escalating doses of up to 30 micrograms of TOLAMBA. Some patients received two additional booster shots of TOLAMBA prior to the 2005 ragweed season. The primary endpoint of this trial is the change in nasal symptoms (i.e., congestion, runny nose, itchy nose, sneezing) relative to placebo following the 2005 ragweed season.

In early 2006, we announced results from a two-year Phase II/III clinical trial of TOLAMBA showing that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptoms scores (TNSS) from baseline during the two-week peak season compared to placebo-treated patients in the first year of the trial (21.2% effect,  $p=0.04$ ) and in the second year of the trial (28.5% effect,  $p=0.02$ ). The treatment effect was achieved on top of a background of antihistamine and decongestant use. The group receiving a single course of TOLAMBA achieved a statistically significant reduction in major secondary endpoints such as hayfever composite score ( $p=0.04$ ) as well as a reduction in antihistamine use and in decongestant use ( $p=0.04$  and  $p=0.03$ , respectively). Results showed that a booster dose prior to the second season (2005) was not required to achieve clinical benefits. Unlike the TOLAMBA-treated group, the boosted group did not achieve statistical significance relative to the efficacy endpoints compared to placebo. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

The Company has recently discussed the TOLAMBA program with the U.S. Food & Drug Administration (FDA). The Company has decided to conduct an additional major safety and efficacy trial with the goal of determining whether a more intensive, single-course dosing regimen can elicit an even greater treatment effect than prior regimens. This trial is anticipated to start by the beginning of the second quarter 2006 to take advantage of the 2006 ragweed season. We plan to conduct the trial as a multi-center, well-controlled study and evaluate the results after both the 2006 and 2007 ragweed seasons. The trial broadens the TOLAMBA clinical program and is designed to complement data derived from the Company's recently completed Phase II/ III clinical trial and its ongoing trial in ragweed allergic children initiated in 2005. The Company's goal is to discuss the pathway to registration with the FDA following receipt of results from the first year of this trial.

***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 seasonal 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.

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***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 Seasonal Allergy Immunotherapy Candidates**

As TOLAMBA progresses through clinical development, we intend to produce similar ISS-allergen linked product candidates for the treatment of other major seasonal 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 major cedar tree allergens, Cry j 1 and Cry j 2, can be linked to ISS. As with TOLAMBA, 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.

TOLAMBA and our other seasonal allergy products should be well positioned to compete against not only currently available immunotherapies, but also other interventions targeting the symptoms of seasonal allergic rhinitis. We believe that our additional seasonal allergy products will present the same advantages over symptomatic interventions as described for TOLAMBA. As a result of these advantages and by providing a broader set of seasonal 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

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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 byproducts. 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.

### **License and Development Agreement with UCB**

In March 2005, we agreed to end the collaboration with UCB Farchim, S.A., a subsidiary of UCB, S.A. (UCB), and regained full rights to our allergy program. We assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to TOLAMBA and for preclinical development programs in grass and in peanut allergy.

## **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.

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

Results from Phase I and from Phase II trials showed that HEPLISAV was well tolerated and induced more rapid immunity with fewer immunizations in both healthy young and older adults than Engerix-B<sup>®</sup>, a major currently available vaccine. Our Phase I 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 II trial in Canada evaluating the efficacy of two injections of our vaccine candidate (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 show that our vaccine induces 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

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have completed a Phase II/ III 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 Phase II/ III trial was conducted in an older adult population, aged 40-70 years, in whom achieving seroprotection with conventional vaccine is more difficult than in younger adults. 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.

We initiated a pivotal Phase III clinical trial of HEPLISAV in June 2005. This trial involves 400 subjects, aged 40-70, and is being conducted in Asia. We are in the process of planning additional trials designed to support registration activities. We initiated a Phase I trial in pre-dialysis patients in the U.S. in October 2005. The Company also plans to conduct additional trials in selected high-risk populations.

***Commercial Opportunity***

Hepatitis B is a common chronic infectious disease with an estimated 350 million chronic carriers worldwide. Prevention of hepatitis caused by the hepatitis B virus 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.

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.

***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.

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### **Hepatitis B Therapy**

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

Our hepatitis B therapeutic candidate, in which advanced ISS is both linked to and combined with hepatitis B surface antigen, 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.

#### ***Preclinical Status***

Preclinical experiments in mice have shown that our product candidate for hepatitis B therapy redirects the immune response toward Th1-based immunity, producing strong interferon-gamma and cytotoxic T cell responses. Interferon-gamma and cytotoxic T cell responses are thought to be important for the control and/or elimination of chronic hepatitis B infection.

#### ***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 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, both interferon-alpha and antiviral drugs are expensive and may induce significant side effects. In addition, patients typically become resistant to antiviral drugs within one year of initiating treatment, ultimately rendering them ineffective as long-term therapies.

#### ***License and Supply Agreement with Berna Biotech***

In October 2003, we entered into an agreement with Berna Biotech, a publicly traded company based in Bern, Switzerland, in which Berna agreed to supply us with its proprietary hepatitis B surface antigen for use in our Phase III clinical trials for our hepatitis B vaccine and, if merited, its subsequent commercialization. According to terms of the agreement, we will receive adequate supplies of hepatitis B surface antigen for clinical development, and then will pay fixed amounts for use of the antigen in the potential commercial vaccine. In 2006, Berna was acquired by Crucell N.V. We do not expect the acquisition to have any impact on our ability to receive the agreed upon supply of hepatitis B surface antigen.

### **Chronic Inflammation**

#### **Asthma**

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

In most people, asthma is an allergic inflammatory 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 to produce specific long-term immunity. We anticipate that ISS would be administered initially on a weekly basis. Once the immune response to

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asthma-causing allergens has been reprogrammed to a Th1 response, it may be possible to reduce administrations of ISS to longer periodic intervals or only as needed. In addition, based on preclinical data, we believe that this therapy may lead to reversal of airway remodeling caused by asthma.

### ***Clinical Status***

We have an inhaled therapeutic product candidate for treatment of asthma, which has completed a Phase IIa trial in Canada. We are performing additional preclinical work to optimize the route of administration and regimen for the asthma clinical program and have postponed additional clinical trials in asthma.

### **Additional Programs**

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

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

##### ***Anthrax***

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 \$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.

##### ***Human Viral Influenza***

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 influenza-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 nucleoprotein, one of the flu antigens that varies little from year to year, and then adds it to conventional vaccine to augment its activity. We believe that linked ISS-nucleoprotein added to conventional vaccine will not only increase antibody responses capable of blocking viral infections but also confer protective immunity against divergent influenza strains. We have demonstrated that a single ISS-linked nucleoprotein product can protect mice from challenge with widely divergent influenza virus strains. In the third quarter of 2003 we were awarded a \$3.0 million grant over three and a half years to fund



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research and development of an advanced pandemic influenza vaccine under an NIAID program for biodefense administered by the National Institutes of Health.

### **Cancer**

We are evaluating the potential of 1018 ISS to enhance the cytotoxic effects of monoclonal antibodies on cancer cells. This strategy has been shown to be effective in preclinical models utilizing various anticancer monoclonal antibodies. We have conducted an open-label Phase I, dose-escalation trial of 1018 ISS in combination with Rituxan in 20 patients with a cancer of the blood called non-Hodgkin's lymphoma (NHL) to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of 1018 ISS administered in combination with Rituxan. Results of this study showed interferon-alpha/beta inducible gene expression, without significant toxicity. These results provide a rationale for further testing of this combination immunotherapy approach to NHL.

### **Antiviral Applications**

Increasing the resistance of individuals to a wide range of potential pathogens by stimulating their innate immune response would provide a complementary approach to vaccination against specific pathogens. As the most likely route of exposure to biological weapons is through the air, stimulation of innate immune mechanisms in the lungs would be particularly important.

We have shown in animal models that ISS enhances innate immunity and increases resistance to a variety of pathogens in both prophylactic and therapeutic settings. We are currently evaluating the effects of advanced ISS as prophylaxis against a broad spectrum of biological agents in both mouse and primate models. In the third quarter of 2003, we were awarded an NIAID biodefense grant of \$1.7 million over two and one-half years. This grant will fund research and development of a product candidate using pulmonary delivery to elicit prophylactic innate immunity to airborne biological agents.

### **Chronic Inflammation**

We are conducting preclinical studies on a novel class of chemical compounds called thiazolopyrimidines, or TZPs, for the potential treatment of inflammatory diseases. Tumor necrosis factor (TNF) alpha is a cytokine that plays a major role in the body's response to infectious diseases. TZPs are our proprietary small molecules that inhibit the production of TNF-alpha and IL-12. They appear to have a novel mechanism of action, including a high degree of specificity, increasing their potential to be used as drugs. Based on the outcome of these preclinical studies, we will determine a potential clinical application for this approach.

### **Autoimmune Disorders**

We have pioneered a new approach to treating autoimmune disease based upon a novel class of oligonucleotides, named immunoregulatory sequences (IRS), that specifically inhibit the toll-like receptor (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 the Company's novel IRS technology.

### **Intellectual Property**

Our intellectual property portfolio can be divided into four main technology areas: ISS, TZP, 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 three technology areas.

*ISS technology:* We have 29 issued U.S. and foreign patents, 31 pending U.S. patent applications, and 101 pending foreign applications that seek worldwide coverage of compositions and methods

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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.

*TNF-alpha inhibitors:* We have 22 issued U.S. and foreign patents and 4 pending U.S. and foreign patent applications providing worldwide rights to a group of small-molecule TNF-alpha synthesis inhibitors including TZPs. We hold exclusive, worldwide licenses to these patents and patent applications held by the Regents of the University of California.

*Vaccines using DNA:* We have 24 issued U.S. and foreign patents and 6 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.

*Immunoregulatory sequences (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 default for failure to make royalty payments, produce required reports or fund internal research and we do not cure a breach within 60 days after being notified of the breach. Otherwise, the agreements do not terminate 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 is abandoned, except for the TZP agreement, which will expire on such date or in October 2013, whichever is later.

Although we believe our patents and patent applications, including those that we license, provide a competitive advantage, the patent positions of pharmaceutical and biopharmaceutical companies are highly uncertain and involve complex legal and factual questions. We and our collaborators or licensors may not be able to develop patentable products or be able to obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. These current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. Patent applications filed before November 29, 2000 in the U.S. are maintained in secrecy until patents issue; later filed U.S. applications and patent applications in most foreign countries generally are not published until at least 18 months after they are filed. Scientific and patent publication often occurs long after the date of the scientific discoveries disclosed in those publications. Accordingly, we cannot be certain that we were the first to invent the subject matter covered by any patent application or that we were the first to file a patent application for any inventions.

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

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existence of third-party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection.

If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from pursuing research, development or commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. 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, including TOLAMBA and HEPLISAV. In December 2003 the U.S. Patent and Trademark Office declared an interference to resolve first-to-invent disputes between a patent application filed by the Regents of the University of California, which is exclusively licensed to us, and an issued U.S. patent owned by Coley relating to immunostimulatory DNA sequences. The declaration of interference named the Regents of the University of California as senior party, indicating that a patent application filed by the Regents of the University of California and licensed to us was filed prior to a patent application owned by Coley that led to an issued U.S. patent. The interference provides the first forum to challenge the validity and priority of certain of Coley's patents. On March 10, 2005, the U.S. Patent and Trademark Office issued a decision in the interference which did not address the merits of the case, but dismissed it on a legal technicality related to the timing of Dynavax's filing of its claims and request for interference. Dynavax has appealed this decision. If we prevail in the appeal, we will be able to continue the interference to address the merits of the case. If we prevail in the interference proceeding, it would establish our founders as the inventors of the inventions in dispute. However, even a favorable outcome in the interference would not prevent Coley from asserting its other patents or patent claims that were not the subject of the interference, against our ISS products, which could harm our ability to commercialize those products. If we do not prevail in the interference proceeding, we may not be able to obtain patent protection on the subject matter of the interference, which would have a material adverse impact on our business. In addition, if Coley prevails in the interference, it may seek to enforce its rights under issued claims, including, for example, by suing us for patent infringement. Consequently, we may need to obtain a license to issued and/or pending claims held by Coley by paying cash, granting royalties on sales of our products or offering rights to our own proprietary technologies. Such a license may not be available to us on acceptable terms, if at all.

We could incur substantial costs if:

litigation is required to defend against patent suits brought by third parties;

we participate in patent suits brought against or initiated by our licensors;

we initiate similar suits; or

we pursue an interference proceeding.

In addition, we may not prevail in any of these actions or proceedings. An adverse outcome in litigation or an interference or other proceeding 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.



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We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions agreement before beginning their employment, consulting or advisory relationship with us. These agreements generally provide that the individuals must keep confidential and not disclose to other parties any 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 services to us.

In the future, we may collaborate with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, licensors, scientific collaborators and consultants. In addition, other parties may circumvent any proprietary protection we do have. As a result, we may not be able to maintain our proprietary position.

### **Manufacturing**

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 contract manufacturer to produce our ISS for clinical trials. We have identified several additional manufacturers with whom we could contract for the manufacture of ISS.

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, including grass, tree and plant 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 currently planned Phase III clinical trial. We plan to qualify and enter into manufacturing agreements with one or more new commercial manufacturers to produce additional supplies of TOLAMBA as required for completion of clinical trials and commercialization.

HEPLISAV consists of ISS combined with GMP hepatitis B surface antigen using standard formulation processes. Hepatitis B surface antigen is manufactured worldwide by several companies. We have acquired hepatitis B surface antigen for our clinical trials to date from a single commercial manufacturer. We entered into a license and supply agreement with Berna Biotech (acquired by Crucell N.V.), under which Berna will provide a supply of antigen necessary to permit us to commence our planned Phase III trials and to commercialize HEPLISAV.

### **Marketing**

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

### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many of our competitors, including biotechnology and pharmaceutical companies, academic institutions and other research organizations, are

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actively engaged in the discovery, research and development of products that could compete directly or indirectly with our products under development.

If TOLAMBA is approved and commercialized, it 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, Allergy Therapeutics and Cytos are developing enhanced allergy immunotherapeutic products formulated for both injection and sublingual delivery. We believe that our TOLAMBA program for ragweed allergy is the more advanced and, if developed, approved and commercialized, could reach the market ahead of these other products. A number of companies, including GlaxoSmithKline Plc, Merck & Co., Inc., and AstraZeneca Plc, produce pharmaceutical products, such as antihistamines, corticosteroids and anti-leukotriene agents, which manage seasonal 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 hepatitis B vaccine, if it is approved and commercialized, will compete directly with existing, three-injection vaccine products produced by Merck & Co., Inc., GlaxoSmithKline Plc, and Berna Biotech AG (acquired by Crucell N.V.), among others. There are also two-injection hepatitis B vaccine products in clinical development, including a vaccine being developed by GlaxoSmithKline Plc. In addition, our hepatitis B vaccine 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., GlaxoSmithKline Plc and other companies.

Our inhaled 1018 ISS asthma product candidate would indirectly compete with existing asthma therapies, including corticosteroids, leukotriene inhibitors and IgE monoclonal antibodies, including those produced by Novartis Corporation, AstraZeneca Plc, Schering-Plough Corporation and GlaxoSmithKline Plc. 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 Aventis Group under a collaboration agreement with Coley Pharmaceutical Group. 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.

We expect that competition among products approved for sale will primarily be based on the efficacy, ease of use, safety profile, and price. Our ability to compete effectively, develop products that can be manufactured cost-effectively and market them successfully based on differentiated label claims will depend on our ability to:

- show efficacy and safety in our clinical trials;
- obtain required government and other public and private approvals on a timely basis;
- enter into collaborations to manufacture, market and sell our products;
- maintain a proprietary position in our technologies and products; and
- attract and retain key personnel.





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### **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 products are subject to rigorous review by the Food and Drug Administration (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:

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 are often not 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 clinical trials and as result of many factors, certain of which are not under our control, including:

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;



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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 I 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 II trials, the product candidate is introduced into patients who suffer from the medical condition that the product candidate is intended to treat. Phase II 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 II evaluations demonstrate that a product candidate appears to be both safe and effective, Phase III 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 III 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 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.



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At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are mandatory for biotechnology and some other novel 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, 2006, we had 77 full-time employees, including 16 Ph.D.s, 2 M.D.s and 13 others with advanced degrees. Of the 77 employees, 55 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.

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

### **Risk Factors**

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

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

We have experienced significant operating losses in each year since our inception in August 1996. To date, our revenue has resulted from a collaboration agreement with UCB Farchim, S.A. (UCB) and government and private agency grants. The UCB collaboration agreement ended in March 2005. The grants are subject to annual review based on the achievement of milestones and other factors and will terminate in January 2007 at the latest. Our accumulated deficit was \$115.9 million as of December 31, 2005, and we anticipate that we will incur substantial additional operating losses for the foreseeable future. These losses have been, and will continue to be, principally the result of the various costs associated with our research and development activities. We expect our losses to increase primarily as a consequence of our continuing product development efforts.

We do not have any products that generate revenue. In early 2006, we announced results from a two-year Phase II/III clinical trial for TOLAMBA, an immunotherapy for ragweed allergy, and in 2005 we initiated a trial of TOLAMBA in ragweed allergic children. In 2005, we also completed a Phase II/III trial for HEPLISAV in Singapore and initiated a pivotal Phase III trial for HEPLISAV in Asia. These and our other product candidates may never be commercialized, and we may never generate product-related revenue. Our ability to generate product revenue depends upon:

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

obtaining regulatory approvals for our product candidates in the United States and international markets;

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entering into collaborative relationships on commercially reasonable terms for the development, manufacturing, sales and marketing of our product candidates, and then successfully managing these relationships; and

obtaining commercial acceptance of our products, in particular TOLAMBA and HEPLISAV.

If we are unable to generate revenues or achieve profitability, we may be required to significantly reduce or discontinue our operations or raise additional capital under adverse circumstances.

**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 our product candidates, potentially commercialize them and generate revenues, we may require substantial additional capital resources in order to continue our operations, and any such funding may not cover our costs of operations. In the event we change our development plans or clinical programs, we may need additional capital sooner than we currently anticipate.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. We may be unable to obtain additional capital from financing sources or from agreements with collaborators on acceptable terms, or at all. If at any time sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate some or all of our research, preclinical or clinical programs or discontinue our operations.

**All of our product candidates are unproven, and our success depends on our product candidates being approved through uncertain and time-consuming regulatory processes. Failure to prove our products safe and effective in clinical trials and obtain regulatory approvals could require us to discontinue operations.**

None of our product candidates has been approved for sale in the United States or any foreign market. 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 TOLAMBA, our ragweed allergy product candidate, and HEPLISAV, our hepatitis B vaccine product candidate. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources. Product development failure can occur at any stage of clinical trials and as a result of many factors, many of which are not under our control.

We will need to demonstrate in clinical trials that each product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. In early 2006, we announced results from a two-year Phase II/ III clinical trial of TOLAMBA. The safety profile of TOLAMBA was favorable. The Company has recently discussed the TOLAMBA program with the FDA and plans to conduct an additional major safety and efficacy trial in the second quarter of 2006 designed to complement data derived from the recently completed Phase II/ III clinical trial and the ongoing trial in ragweed allergic children initiated in 2005. We plan to conduct the trial as a multi-center, well-controlled study and evaluate the results after both the 2006 and 2007 ragweed seasons. If we identify any safety issues associated with TOLAMBA, we may be forced to terminate or suspend our ongoing pediatric trial, and we may be delayed or prevented from initiating a pivotal Phase III trial for TOLAMBA. We have initiated a pivotal Phase III trial for HEPLISAV in Asia. We are in the process of planning additional trials designed to support registration activities. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval in their jurisdictions.

Many new drug candidates, including many drug candidates that have completed Phase III 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 never guaranteed. Failure to complete clinical trials and prove that our products are safe and

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effective would have a material adverse effect on our ability to eventually generate revenues and could require us to reduce the scope of or discontinue our operations.

**Our clinical trials may be 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 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, notably TOLAMBA, is limited due to the seasonal nature of ragweed allergy. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the next appropriate season, which could result in a delay of an entire year. Our registration and commercial timelines will be dependent on results of the current and planned clinical trials and further discussions with the FDA. Consequently, we may experience additional delays in obtaining regulatory approval for these product candidates.

Suspension, termination or unanticipated delays of our clinical trials for TOLAMBA or HEPLISAV may:

adversely affect our ability to commercialize or market any product candidates we may develop;

impose significant additional costs on us;

potentially diminish any competitive advantages that we may attain;

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 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, proprietary technologies or the licenses on which we rely, 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 another party's proprietary rights. 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 expenses and it will divert the efforts of our technical and management personnel. Others may succeed in challenging the validity of our issued and pending claims.

Two of our potential competitors relative to HEPLISAV, Merck & Co., Inc. and GlaxoSmithKline Plc, 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 were to commercialize HEPLISAV in the United States, Merck and/or GlaxoSmithKline 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



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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. A license may require us to pay substantial royalties, require us to grant a cross-license to our technology or may not be available to us on acceptable terms or on any terms. 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 may require us to change our business strategy and could reduce the value of our business.

Another of our potential competitors, Coley Pharmaceutical Group (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, including TOLAMBA and HEPLISAV. In December 2003 the U.S. Patent and Trademark Office declared an interference to resolve first-to-invent disputes between a patent application filed by the Regents of the University of California, which is exclusively licensed to us, and an issued U.S. patent owned by Coley relating to immunostimulatory DNA sequences. The declaration of interference named the Regents of the University of California as senior party, indicating that a patent application filed by the Regents of the University of California and licensed to us was filed prior to a patent application owned by Coley that led to an issued U.S. patent. The interference provides the first forum to challenge the validity and priority of certain of Coley's patents. On March 10, 2005, the U.S. Patent and Trademark Office issued a decision in the interference which did not address the merits of the case, but dismissed it on a legal technicality related to the timing of Dynavax's filing of its claims and request for interference. Dynavax has appealed this decision. If we prevail in the appeal, we will be able to continue the interference to address the merits of the case. If we prevail in the interference proceeding, it would establish our founders as the inventors of the inventions in dispute. However, even a favorable outcome in the interference would not prevent Coley from asserting its other patents or patent claims, that were not the subject of the interference, against our ISS products, which could harm our ability to commercialize those products. If we do not prevail in the interference proceeding, we may not be able to obtain patent protection on the subject matter of the interference, which would have a material adverse impact on our business. In addition, if Coley prevails in the interference, it may seek to enforce its rights under issued claims, including, for example, by suing us for patent infringement. Consequently, we may need to obtain a license to issued and/or pending claims held by Coley by paying cash, granting royalties on sales of our products or offering rights to our own proprietary technologies. Such a license may not be available to us 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, which may be costly and subject us to various enforcement actions.**

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, resulting in limitations on our labeling indications or marketing claims, or withdrawn completely if problems occur after commercialization. Thus, even if we receive FDA and other regulatory approvals, our product candidates may later exhibit qualities that limit or prevent their widespread use or that force us to withdraw those products from the market.

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.

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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 1018 ISS, 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, potential collaborators may also be reluctant to establish collaborations for our products in distinct therapeutic areas due to the common safety risk across therapeutic areas. If adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to discontinue our operations. **A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may be unsuccessful in establishing and managing 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. We have established a collaborative relationship with Berna Biotech (acquired by Crucell N.V.) for HEPLISAV, a prophylactic vaccine, and for hepatitis B therapeutic product candidates. Our collaboration agreement with UCB for TOLAMBA and for grass allergy immunotherapy ended in March 2005. Future collaboration revenue will depend on our ability to enter into new collaborative relationships.

The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

**We rely on third parties to supply component materials necessary for our clinical product candidates and manufacture product candidates for our clinical trials. Loss of these suppliers or manufacturers, or failure to replace them may delay our clinical trials and research and development efforts and may result in additional costs, which would preclude us from producing our product candidates on commercially reasonable terms.**

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

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We and these third parties are required to comply with applicable current FDA good manufacturing practice regulations and similar requirements in Canada and other foreign countries. 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 must pass a pre-approval inspection before we can obtain regulatory approval for any of our product candidates.

In particular, we have relied on a single supplier to produce our ISS for clinical trials. ISS is a critical component of both of TOLAMBA and HEPLISAV. 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 an in-house ISS manufacturing capability, incurring 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.

In addition, we do not currently have a contract manufacturer for TOLAMBA or sufficient TOLAMBA to supply our potential commercial needs. We are currently manufacturing supplies of TOLAMBA for the second year of our current clinical trial in ragweed allergic children. We intend to enter into manufacturing agreements with one or more commercial-scale contract manufacturers to produce additional supplies of TOLAMBA as required for new clinical trials and commercialization. If we are unable to complete such agreements, we may be unable to commence and complete our clinical trials in a timely fashion, and we would have to establish an internal commercial scale manufacturing capability for TOLAMBA, incurring increased capital and operating costs, delays in the commercial development of TOLAMBA and higher manufacturing costs than we have experienced to date.

**We have or intend to contract with one or more third parties to conduct our clinical trials for TOLAMBA and HEPLISAV. If these third parties do not carry out 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 TOLAMBA or HEPLISAV.**

We are unable to independently conduct our planned clinical trials for TOLAMBA or HEPLISAV, and we have or intend to contract with third party contract research organizations to manage and conduct these trials. If these third parties do not carry out their contractual duties or obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to failure to adhere to our clinical protocols or for other reasons, our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our trials would delay our ability to commercialize TOLAMBA or HEPLISAV and generate revenues.

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

If we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our product candidates 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 constrain our marketing claims, reducing our or our collaborators ability to market the benefits of our products to particular patient populations. If we are unable to successfully market any approved product candidates, or are limited in our marketing efforts by regulatory limits on labeling indications or marketing claims, our ability to generate revenues could be significantly impaired.

In particular, treatment with TOLAMBA, if approved, will require a series of injections, and we expect that some of the patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider using our product. We believe that market acceptance of TOLAMBA will also depend on our ability to offer competitive pricing, increased efficacy and improved ease of use as compared to existing or potential new allergy treatments.

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We may seek partners for purposes of commercialization of HEPLISAV in selected markets worldwide in addition to or as a replacement for our current collaborative partner, Berna Biotech (acquired by Crucell N.V.). Berna Biotech has an exclusive option to commercialize HEPLISAV and therapeutic product candidates. 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.

**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 generate revenues from the sales of any approved product candidates in excess of the costs of producing the product candidates will depend in part on the availability of 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. Significant uncertainty therefore exists as to coverage and reimbursement levels for newly approved health care products, including pharmaceuticals. 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 the considerable capital resources we have spent and will continue to spend on product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investment in product development. If it becomes apparent, due to changes in coverage or pricing of pharmaceuticals in our market or a lack of reimbursement, that it will be difficult, if not impossible, for us to generate revenues in excess of costs, we will need to alter our business strategy significantly. This could result in significant unanticipated costs, harm our future prospects and reduce our stock price.

**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 many companies and institutions, including pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing alternative therapies to treat or prevent allergy, infectious diseases, 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.

TOLAMBA, if approved, will compete directly with conventional allergy shots and indirectly with antihistamines, corticosteroids and anti-leukotriene agents, used to treat seasonal allergy symptoms, including those produced by GlaxoSmithKline Plc, Merck & Co., Inc. and AstraZeneca Plc. Since our TOLAMBA ragweed allergy treatment would require a series of injections, we expect that some patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider our product.

HEPLISAV, if approved, will compete with existing vaccines produced by GlaxoSmithKline Plc and Merck & Co., Inc., among others.

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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 with existing and potential competitors we may not be able to obtain financing, 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 of these people, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

**We intend to 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 HEPLISAV and therapeutic product candidates.**

We plan to introduce HEPLISAV initially in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States could impose substantial burdens on our resources and divert management's attention from domestic operations. We may also conduct operations in other foreign jurisdictions.

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;

securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

difficulties and costs associated with complying with a wide variety of complex international laws and treaties;

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 HEPLISAV and therapeutic product candidates, as well as other product candidates that we may choose to commercialize internationally, which would impair our ability to generate revenues.

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

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials.

However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

**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.

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

Our success depends on our ability to:

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

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

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

The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty, given that 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.

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

we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

we might not have been the first to file patent applications for these inventions;

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

our issued patents may not provide a basis for commercially viable products 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 companies, universities or research institutions may harm our ability to do business;

other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and

other companies, universities or research institutions 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 leak of confidential data into 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 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 success depends upon our license arrangements with the Regents of the University of California. These licenses are critical to our research and product development efforts. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the invention and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and the Regents of the University of California, or scientific collaborators. Additionally, our agreements with the Regents of the University of California generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow the Regents of the University of California to terminate any of these licensing agreements or convert them to non-exclusive licenses. In addition, our license agreements with the Regents of the University of California 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.

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

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

progress or results of any of our clinical trials, in particular any announcements regarding the progress or results of our planned Phase III trials for TOLAMBA and HEPLISAV;

progress of regulatory approval of our product candidates, in particular TOLAMBA and HEPLISAV, and compliance with ongoing regulatory requirements;

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

market acceptance of our product candidates;

our ability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;

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 form strategic partnerships or joint ventures;

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

changes in government regulations;

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

general economic conditions and other external factors;

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

degree of trading liquidity 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

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price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

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

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

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

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

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

In addition, we are subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

**We will continue to implement additional finance and accounting systems, procedures or controls as we grow our business and organization and to satisfy new reporting requirements.**

As a public company, 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 and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control reporting. If we are unable to maintain an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our internal controls over financial reporting and the reliability of our financial statements, which could harm our business and could impact the market price of our common stock.

**The adoption of Statement of Financial Accounting Standard No. 123R and changes to existing accounting pronouncements, rules or practices may affect how we conduct our business and affect our reported financial results.**

On December 16, 2004, the Financial Accounting Standards Board issued Financial Accounting Standard (SFAS) No. 123R (revised 2004), Share-Based Payment which will require us to measure compensation costs for all stock-based compensation at fair value. We will adopt SFAS 123R as of January 1, 2006. Adoption of SFAS 123R will have a material impact on our financial statements, as we will be required to record compensation expense in our statement of operations for stock option grants and stock purchases under our employee stock purchase plan, rather than disclose the impact on our net loss within our footnotes, as is our current practice. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. Changes to existing rules, current practices, or future changes, if any, may adversely affect our reported financial results or the way we conduct our business.

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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

The Company leases approximately 67,000 square feet of laboratory and office space in Berkeley, California, under agreements expiring in September 2014, of which approximately 13,000 square feet is subleased through August 2007. The lease can be terminated at no cost to the Company in September 2009 but otherwise extends automatically until September 2014.

**ITEM 3. LEGAL PROCEEDINGS**

None.

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

None.

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

Our common stock is traded on the Nasdaq Stock Market under the symbol **DVAX**. Public trading of our common stock commenced on February 19, 2004. Prior to that, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sale prices per share of our common stock on the Nasdaq Stock Market.

	<b>Common Stock Price</b>	
	<b>High</b>	<b>Low</b>
<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
<b>2004</b>		
First Quarter	\$ 9.98	\$ 7.10
Second Quarter	\$ 9.35	\$ 5.14
Third Quarter	\$ 6.87	\$ 4.02
Fourth Quarter	\$ 8.80	\$ 4.75

As of February 28, 2006, there were approximately 97 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 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 an aggregate offering price 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. The underwriters for the initial public offering were Bear, Stearns & Co. Inc., CIBC World Markets Corp. and Pacific Growth Equities LLC. We received net proceeds from the offering of approximately \$33.1 million. These proceeds were net of \$2.1 million in underwriting discounts and commissions, \$0.4 million in legal, accounting and printing fees and \$0.1 million in other expenses. We intend to use the proceeds from this offering for general corporate purposes, including clinical trials, research and development expenses and general and administrative expenses.

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 an aggregate offering price 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. The underwriters for the initial public offering were Bear, Stearns & Co. Inc., Deutsche Bank Securities Inc. and Piper Jaffray & Co. We received net proceeds from the offering of



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approximately \$46.5 million. These proceeds were net of \$3.6 million in underwriting discounts and commissions, \$1.4 million in legal, accounting and printing fees and \$0.3 million in other expenses. We used \$0.4 million of the net proceeds to make a one-time cash payment to the University of California pursuant to the terms of several license agreements with them.

We will 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, 2005, 2004 and 2003 and the Consolidated Balance Sheets Data as of December 31, 2005 and 2004 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, 2002 and 2001 and the Consolidated Balance Sheets Data as of December 31, 2003, 2002 and 2001 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.

**Years Ended December 31,**

**2005                      2004                      2003                      2002                      2001**

**(In thousands, except per share data)**

**Consolidated Statements of Operations Data:**

Collaboration and grant revenues	\$ 14,655	\$ 14,812	\$ 826	\$ 1,427	\$ 2,359
Operating expenses:					
Research and development	27,887	23,129	13,786	15,965	17,363
General and administrative	9,258	8,543	4,804	4,121	4,527
Total operating expenses	37,145	31,672	18,590	20,086	21,890
Loss from operations	(22,490)	(16,860)	(17,764)	(18,659)	(19,531)
Interest income, net	1,935	889	412	621	1,119
Deemed dividend			(633)		
Net loss attributable to common stockholders	\$ (20,555)	\$ (15,971)	\$ (17,985)	\$ (18,038)	\$ (18,412)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.79)	\$ (0.75)	\$ (10.04)	\$ (10.65)	\$ (12.29)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	25,914	21,187	1,791	1,694	1,498

**December 31,**

**2005                      2004                      2003                      2002                      2001**

**(In thousands)**

**Consolidated Balance Sheets Data:**

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Cash, cash equivalents and marketable securities	\$ 75,110	\$ 65,844	\$ 29,097	\$ 29,410	\$ 11,757
Working capital	71,941	64,017	26,340	25,913	9,498
Total assets	80,093	73,646	31,585	31,478	15,117
Minority interest in Dynavax Asia			14,733		
Mandatorily redeemable convertible preferred stock					45,479
Convertible preferred stock			83,635	83,635	5,799
Accumulated deficit	(115,891)	(95,336)	(79,365)	(62,013)	(43,975)
Total stockholders' equity (net capital deficiency)	74,363	59,876	(71,932)	(56,371)	(40,216)



**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 under federal securities laws. Forward-looking statements are not guarantees of future performance and 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 this Item, Item 1 Business, as well as those discussed elsewhere in this document 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**

We discover, develop and intend to commercialize innovative products to treat and prevent allergies, infectious diseases and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences that we believe enhance the ability of the immune system to fight disease and control chronic inflammation. The most advanced clinical programs in Dynavax's ISS-based pipeline are a ragweed allergy immunotherapeutic and a hepatitis B vaccine.

We have developed a novel injectable product candidate to treat ragweed allergy that we call TOLAMBA<sup>™</sup> (formerly, Amb a 1 ISS Conjugate or AIC). In early 2006, we announced results from a two-year Phase II/ III clinical trial of TOLAMBA showing that patients treated with TOLAMBA experienced a statistically significant reduction in total nasal symptom scores compared to placebo-treated patients in the second year of the trial. The safety profile of TOLAMBA was favorable. The Company has recently discussed the TOLAMBA program with the U.S. Food & Drug Administration (FDA). The Company has decided to conduct an additional major safety and efficacy trial with the goal of determining whether a more intensive, single-course dosing regimen can elicit an even greater treatment effect than prior regimens. This trial is anticipated to start by the beginning of the second quarter 2006 to take advantage of the 2006 ragweed season. The trial broadens the TOLAMBA clinical program and is designed to complement data derived from the Company's recently completed Phase II/ III clinical trial and its ongoing trial in ragweed allergic children initiated in 2005. The Company's goal is to discuss the pathway to registration with the FDA following receipt of results from the first year of this trial.

We have developed a product candidate for hepatitis B prophylaxis called HEPLISAV<sup>™</sup>. A Phase II/ III trial in subjects who are more difficult to immunize with conventional vaccines conducted in Singapore has been completed. 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 Engerix-B<sup>®</sup>, a major currently available vaccine. In June 2005, we initiated a pivotal Phase III trial in the older, more difficult to immunize population in Asia. We are in the process of planning additional trials designed to support registration activities. We believe that strategic opportunities for HEPLISAV exist in key global markets. Our initial commercialization strategies will likely target these markets and focus on high-value, underserved populations. These populations include pre-hemodialysis patients, HIV and Hepatitis C Virus (HCV) positive patients, other populations with compromised immune systems as well as professionals in healthcare and law enforcement for whom achieving seroprotection quickly is critical. In October 2005, we announced the initiation of a U.S.-based Phase I clinical trial of HEPLISAV in patients with end-stage renal failure (pre-hemodialysis).

For the year ended December 31, 2005, our net loss attributable to common stockholders was \$20.6 million, compared to \$16.0 million in 2004 and \$18.0 million in 2003. Our operating results for 2005

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reflect the financial impact resulting from the ending of our development and commercialization collaboration with UCB Farchim, S.A. (UCB) that occurred in March 2005. Total revenues for the year ended December 31, 2005 were \$14.7 million, compared to \$14.8 million in 2004 and \$0.8 million in 2003. 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 UCB collaboration. During 2005, 83% of our revenues were derived from our collaboration activities with UCB, while the remaining revenues were earned from government and private agency grants. Our ability to generate future collaboration revenue in 2006 and beyond will be dependent on our ability to enter into new collaborative relationships. Until we enter into new collaboration arrangements, we expect our future revenues will be limited to government and private agency grants, which will be significantly lower than during the period when we had our collaboration agreement with UCB.

As of December 31, 2005, we had an accumulated deficit of \$115.9 million. We do not have any products that generate revenue. We expect to incur substantial and increasing losses as we continue the development of our lead product candidates and preclinical and research programs. If we were to receive regulatory approval for any of our product candidates, we would be required to invest significant capital to develop, or otherwise secure through collaborative relationships, commercial scale manufacturing, marketing and sales capabilities. Even if we are able to obtain approval for our product candidates, we are likely to incur increased operating losses until product sales grow sufficiently to support the organization.

In the fourth quarter of 2005, we completed an underwritten public offering that resulted in net proceeds to the Company of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. We intend to use the proceeds from this offering for general corporate purposes, including clinical trials, research and development expenses and general and administrative expenses.

Excluding the potential impact of any business collaborations or other transactions that may be entered into, we anticipate that our operating expenses will increase significantly during 2006, primarily in connection with our clinical development activities and overall organizational growth.

**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***

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. We recognize collaboration, upfront and other revenue based on the terms specified in the agreements, generally as work is performed or approximating a straight-line basis over the period of the collaboration. Any amounts received in advance of performance are recorded as deferred revenue and amortized over the estimated term of the performance obligation. Revenue from milestones with substantive performance risk

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is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations and milestones is nonrefundable.

Revenues related to government and private agency grants are recognized as the related research expenses are incurred. 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 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***

Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, established accounting and disclosure requirements using a fair value based method of accounting for stock-based compensation plans. We have adopted the pro forma disclosure requirements of SFAS 123, as amended by SFAS 148,

Accounting for Stock-Based Compensation Transition and Disclosure. As permitted under SFAS 123, we continue to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion (APB) No. 25 and its interpretations. We account for stock compensation to non-employees in accordance with SFAS 123, as amended by SFAS 148 and EITF Issue 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.

For options granted to employees, we calculate the difference, if any, between the estimated fair value of our common stock and the option exercise price on the date of grant and record deferred stock compensation as a component of stockholders' equity. The intrinsic value of the options is amortized as a charge to operations using the straight-line method over the option vesting period for employees, ranging up to four years. For options granted to non-employees, we calculate the fair value using the Black-Scholes valuation model on the date of grant and record stock compensation expense ratably over the service period. Periodically, we re-measure the fair value of unvested options granted to non-employees and record a cumulative adjustment to stock compensation expense.

For pro forma disclosure, we estimate the fair value of each employee option and employee purchase right using the Black-Scholes valuation model. The Black-Scholes model was developed for use in estimating the fair value of traded options which have no restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility and expected life of the option. Our expected stock price volatility was estimated

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using the historical closing stock price per day since January 1, 2004, assuming that the daily stock price from January 1, 2004 through the date of our public offering in February 2004 was equal to the initial public offering price per share. Since the Company's initial public offering in February 2004, there has been a limited history of option exercises. As a result, management determined that the most accurate assumption for the expected life of the option is four years, generally based on the vesting cycle of most options. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our stock options.

**Long-lived Assets**

We assess the impairment of long-lived assets, which include property and equipment as well as other assets, whenever events or changes in circumstances indicate that the carrying value may not be recoverable, in accordance with the provisions of SFAS 144, Accounting for the Impairment or Disposal of Long-lived Assets. 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 the 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.

When we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we perform an undiscounted cash flow analysis to determine if impairment exists. If impairment exists, we measure the impairment based on the difference between the asset's carrying amount and its fair value.

**Results of Operations**

The following table sets forth the results of operations for the years ended December 31, 2005, 2004 and 2003 (in thousands, except percentages):

	Years Ended December 31,			Increase (Decrease) from 2004 to 2005		Increase (Decrease) from 2003 to 2004	
	2005	2004	2003	\$	%	\$	%
<b>Results of Operations:</b>							
<b>Revenues:</b>							
Collaboration revenue	\$ 12,199	\$ 13,782	\$	\$ (1,583)	(11)%	\$ 13,782	N/A
Grant revenue	2,456	1,030	826	1,426	138%	204	25%
Total revenues	\$ 14,655	\$ 14,812	\$ 826	\$ (157)	(1)%	\$ 13,986	1,693%
<b>Operating expenses:</b>							
Research and development	\$ 27,887	\$ 23,129	\$ 13,786	\$ 4,758	21%	\$ 9,343	68%
General and administrative	9,258	8,543	4,804	715	8%	3,739	78%

Total operating expenses	\$ 37,145	\$ 31,672	\$ 18,590	\$ 5,473	17%	\$ 13,082	70%
Interest income, net	\$ 1,935	\$ 889	\$ 412	\$ 1,046	118%	\$ 477	116%
Deemed dividend upon issuance of ordinary share of Dynavax Asia	\$	\$	\$ 633	\$	%	\$ (633)	(100)%

**Table of Contents****Revenues**

Total revenues were \$14.7 million for the year ended December 31, 2005 as compared with \$14.8 million for the year ended December 31, 2004. In March 2005, we agreed to end the collaboration with 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. Our ability to generate future collaboration revenue and obtain additional capital will be dependent on our ability to enter into new collaborative relationships. Until we enter into new collaboration arrangements, we expect our future revenues will be limited to government and private agency grants, which will be significantly lower than during the period when we had our collaboration agreement with UCB.

During the second quarter of 2005, the indirect cost rate associated with our grants from the National Institutes of Health (NIH) was approved. As a result, grant revenue for the year ended December 31, 2005 included an increase of \$0.5 million, reflecting the adjustment under the government grant awards from the previously utilized minimum cost overhead rate allowable to the final approved rate.

Total revenues for the years ended December 31, 2004 and 2003 were \$14.8 million and \$0.8 million, respectively. Total revenues in fiscal 2004 were derived primarily from our collaborative agreement with UCB, which was initiated in the first quarter of 2004, compared to revenues for fiscal 2003, which resulted entirely from NIH grants. The NIH awarded the Company grants totaling \$8.4 million in the third quarter of 2003, to be received over as long as three and one-half years to fund research and development of certain biodefense programs.

**Research and Development**

Research and development expense consists primarily of outside services related to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates for our preclinical experiments and clinical trials; compensation and related personnel costs which include benefits, recruitment, travel and supply costs; allocated facility costs and non-cash stock-based compensation. We expense our research and development costs as they are incurred.

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

	Year Ended December 31,			Increase (Decrease) from 2004 to 2005		Increase (Decrease) from 2003 to 2004	
	2005	2004	2003	\$	%	\$	%
<b>Research and Development:</b>							
Compensation and related personnel costs	\$ 8,661	\$ 6,896	\$ 5,721	\$ 1,765	26%	\$ 1,176	21%
Outside services	14,986	12,408	5,405	2,578	21%	7,003	130%
Facility costs	3,673	2,546	1,376	1,127	44%	1,170	85%
Non-cash stock-based compensation	567	1,279	1,284	(712)	(56)%	(5)	%
<b>Total research and development</b>	<b>\$ 27,887</b>	<b>\$ 23,129</b>	<b>\$ 13,786</b>	<b>\$ 4,758</b>	<b>21%</b>	<b>\$ 9,343</b>	<b>68%</b>

Research and development expenses of \$27.9 million 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 primarily due to increased clinical trial and clinical manufacturing activities related to our lead product candidates TOLAMBA and HEPLISAV. During 2005, we incurred costs associated with the second year of the TOLAMBA Phase II/ III clinical trial and the initiation of the clinical trial in ragweed allergic children, as well as the HEPLISAV pivotal Phase III 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.

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Research and development expenses of \$23.1 million for the year ended December 31, 2004 increased by \$9.3 million, or 68%, from the same period in 2003. The increase from fiscal year 2003 was primarily the result of increased clinical trial and clinical manufacturing costs associated with TOLAMBA and HEPLISAV, as well as increased preclinical work associated with government grants for biodefense programs. During 2004, we completed the first year of the TOLAMBA Phase II/ III clinical trial and were conducting a Phase II/ III trial for HEPLISAV. In addition, compensation and related personnel costs rose due to increased headcount. Allocated rent and operating costs increased in conjunction with our move to a new facility in the third quarter of 2004.

We anticipate that our research and development expenses will increase significantly during 2006 in connection with the advancement of our clinical development programs, particularly in the areas of allergy and hepatitis B.

**General and Administrative**

General and administrative expense consists primarily of compensation and related personnel costs, outside services such as accounting, consulting, business development, investor relations and insurance, legal and patent costs, allocated facility costs and non-cash stock-based compensation.

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

	Year Ended December 31,			Increase (Decrease) from 2004 to 2005		Increase (Decrease) from 2003 to 2004	
	2005	2004	2003	\$	%	\$	%
<b>General and Administrative:</b>							
Compensation and related personnel costs	\$ 4,543	\$ 3,322	\$ 2,531	\$ 1,221	37%	\$ 791	31%
Outside services	2,255	1,729	588	526	30%	1,141	194%
Legal and patent costs	1,117	1,291	693	(174)	(13)%	598	86%
Facility costs	510	743	524	(233)	(31)%	219	42%
Non-cash stock-based compensation	833	1,458	468	(625)	(43)%	990	212%
Total general and administrative	\$ 9,258	\$ 8,543	\$ 4,804	\$ 715	8%	\$ 3,739	78%

General and administrative expenses of \$9.3 million for the year ended December 31, 2005 increased by \$0.7 million, or 8%, from the same period in 2004. The increase over the prior year primarily reflects higher compensation and related benefits associated with overall organizational growth. In addition, outside services, including 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. Legal and patent-related costs during the year ended December 31, 2005 were net of \$0.2 million in reimbursable patent interference costs.

General and administrative expenses of \$8.5 million for the year ended December 31, 2004 increased by \$3.7 million, or 78%, from the same period in 2003, primarily reflecting higher costs of operating as a public company. In addition, compensation, benefits and recruitment costs were higher in 2004, primarily associated with the expansion of our management team and overall organizational growth.

We expect general and administrative expenses to increase during 2006, resulting from continued organizational growth and expenses incurred to support the advancement of our clinical development programs.

**Interest Income, Net**

Interest income, net of interest expense and amortization on marketable securities, was \$1.9 million for the year ended December 31, 2005 compared to \$0.9 million reported for the year ended December 31, 2004. The increase was primarily due to the investment in higher yielding marketable securities in 2005 and to a lesser extent, the proceeds from our follow-on equity offering in the fourth quarter of 2005. Interest income, net for the year ended December 31,



2004 rose by \$0.5 million over the \$0.4 million

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reported for the year ended December 31, 2003 as a result of the proceeds from our initial public offering and a higher average marketable securities balance during 2004.

### ***Deemed Dividend***

In October 2003, we completed a sale of 15,200,000 ordinary shares in our subsidiary, Dynavax Asia, to investors. The Company recorded a deemed dividend of \$0.6 million on the difference between the estimated fair value of the common stock at the issuance date and the conversion price of the ordinary shares.

### **Recent Accounting Pronouncements**

On March 29, 2005, the SEC published Staff Accounting Bulletin (SAB) No. 107 regarding the interaction between Financial Accounting Standard (SFAS) No. 123R (revised 2004), Share-Based Payment and certain SEC rules and regulations. On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, which requires all share-based payments to employees to be recognized in the statement of operations. Pro forma disclosure is no longer an alternative. SFAS 123R supersedes Accounting Principles Board (APB) No. 25, Accounting for Stock Issued to Employees, and amends SFAS 95, Statement of Cash Flows.

SFAS 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date. Under SFAS 123R, share-based payments to employees result in a cost that will be measured at fair value on the awards grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised.

We will adopt SFAS 123R as of January 1, 2006. We intend to use the modified prospective transition method of adoption, which requires that we recognize compensation expense on awards that are modified, repurchased or cancelled after the adoption date. When measuring fair value, we plan to continue to use the Black-Scholes option-pricing model. We expect the adoption of SFAS 123R to have a significant negative impact on our results of operations in fiscal 2006 and thereafter, primarily dependent on levels of share-based payments granted in the future as well as our assumptions used to determine fair value. We estimated that the application of SFAS 123R on the outstanding and unvested options at December 31, 2005 (excluding the assumption of any new options granted thereafter) would approximate the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to our Consolidated Financial Statements.

### **Liquidity and Capital Resources**

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 \$177.9 million in net cash proceeds and, to a lesser extent, through amounts received under collaborative agreements and government grants for biodefense programs. We completed an initial public offering in February 2004, raising net proceeds during fiscal 2004 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 to the Company of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. As of December 31, 2005, we had \$75.1 million in cash, cash equivalents and marketable securities. 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.

Cash used in operating activities of \$22.9 million during the year ended December 31, 2005 compared to \$7.3 million for the same period in 2004. 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. Cash used in operating activities during 2004 declined from 2003, primarily resulting from the one-time \$8.0 million upfront payment made to us by UCB in 2004.

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Cash used in investing activities of \$18.7 million during the year ended December 31, 2005 compared to \$46.0 million for the same period in 2004. The decrease in cash usage from the prior year was due primarily to the decline in net purchases of marketable securities. Cash provided by investing activities during 2003 resulted mainly from net maturities of marketable securities during the year.

Cash provided by financing activities of \$33.7 million during the year ended December 31, 2005 compared to \$46.4 million for the same period in 2004. Cash provided by financing activities primarily included the net proceeds from the issuance of common stock in our public offerings during the fourth quarter of 2005 and the first quarter of 2004. Cash provided by financing activities during 2003 resulted mainly from the net proceeds received upon issuance of ordinary shares in Dynavax Asia Pte. Ltd., which became a wholly owned subsidiary upon the closing of our initial public offering in February 2004.

Excluding the potential impact of any equity offerings, business collaborations or other transactions that may be entered into, we expect our cash, cash equivalents and marketable securities to decline by December 31, 2006, primarily due to cash used for operations. We expect net cash used in operating activities to increase significantly in 2006 as compared to prior years related to the advancement of our clinical development programs.

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 it will take for any of our product candidates to complete the clinical trials process, be approved by regulatory authorities and successfully commercialized, we may 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. Capital may become difficult or impossible to obtain due to poor market or other conditions that are outside of our control. 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, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern.

***Contractual Obligations***

The following summarizes our significant contractual obligations as of December 31, 2005 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>Payments Due by Period</b>			
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>
Future minimum payments under our operating lease	\$ 6,498	\$ 1,704	\$ 3,563	\$ 1,231
<b>Total</b>	<b>\$ 6,498</b>	<b>\$ 1,704</b>	<b>\$ 3,563</b>	<b>\$ 1,231</b>

We lease our facility under an operating lease that expires in September 2014. The 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 for a certain portion of the leased space with scheduled payments to us of \$0.4 million annually through 2007. This sublease agreement includes an option for early termination in August 2006 but otherwise extends automatically until August 2007.

The table above excludes certain commitments that are contingent upon future events. The most significant of these contractual commitments that we consider to be contingent obligations are summarized below.



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During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our property lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2005 and is collateralized by a certificate of deposit which has been included in restricted cash in the Consolidated Balance Sheets as of December 31, 2005 and December 31, 2004. Under the terms of the lease agreement, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We rely on research institutions and contract research organizations that conduct and manage clinical trials on our behalf. As of December 31, 2005, under the terms of our agreements with a contract research organization (CRO) and clinical investigator, we are obligated to make future payments as services are provided of approximately \$27 million through 2008. These agreements are terminable by us upon written notice to the CRO. 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.

In March 2005, we agreed to end the collaboration with UCB and regained full rights to our allergy program. We assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to TOLAMBA and for preclinical development programs in grass and in peanut allergy. The March 2005 agreement also provides for the continued partial reimbursement of certain patent interference fees and expenses, if and as incurred by the Company, subject to a maximum amount.

Under the terms of the exclusive license agreements with the Regents of the University of California, we are obligated to pay annual license or maintenance fees and will be required to pay future milestones and royalties on net sales of products originating from the licensed technologies. As partial consideration for the technology licenses, during the first quarter of 2004 we paid one-time charges of \$0.4 million upon the closing of the Company's initial public offering and \$0.2 million related to the collaboration with UCB. No other milestones were achieved as of December 31, 2005.

Under the development collaboration agreement with BioSeek, Inc., we will make various payments based on the success and timing of the Company's signing of a third party partnering agreement where the Company grants to the third party, directly or indirectly, any right or option to market, sell, distribute or otherwise commercialize a thiazolopyrimidine (TZP) product in any geographic territory. During the year ended December 31, 2005, we paid BioSeek \$0.3 million associated with the achievement of a development milestone. No other events occurred that would give rise to payment as of December 31, 2005.

Under the terms of an agreement with Berna Biotech (acquired by Crucell N.V.), we agreed to make certain commercialization and sales milestone payments to Berna regarding the Company's hepatitis B vaccine. None of these milestones were achieved as of December 31, 2005.

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**ITEM 7A. MARKET RISK DISCLOSURE INFORMATION**

**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 no significant investments outside the U.S. and have nominal transactional foreign currency risk because nearly all of our business is transacted in U.S. dollars. As a result, we currently have little exposure to foreign exchange rate fluctuations.

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
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**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, 2005, 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.

In our opinion, management's assessment that Dynavax Technologies Corporation maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2005 and 2004, 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, 2005 of Dynavax Technologies Corporation and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006



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**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, 2005 and 2004, 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, 2005. 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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2005, 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 10, 2006, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

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

	December 31,	
	2005	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,725	\$ 16,590
Marketable securities	66,385	49,254
Restricted cash	408	408
Accounts receivable	689	3,131
Prepaid expenses and other current assets	1,277	1,396
Total current assets	77,484	70,779
Property and equipment, net	2,197	2,465
Other assets	412	402
Total assets	\$ 80,093	\$ 73,646
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 952	\$ 1,391
Accrued liabilities	3,841	4,371
Deferred revenues	750	1,000
Total current liabilities	5,543	6,762
Deferred revenues, noncurrent		6,750
Other long-term liabilities	187	258
Commitments and contingencies		
Stockholders equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2005 and 2004		
Common stock: \$0.001 par value; 100,000 shares authorized at December 31, 2005 and 2004; 30,482 and 24,627 shares issued and outstanding at December 31, 2005 and 2004, respectively	30	25
Additional paid-in capital	192,840	159,074
Deferred stock compensation	(2,467)	(3,366)
Notes receivable from stockholders		(419)
Accumulated other comprehensive loss:		
Unrealized loss on marketable securities available-for-sale	(144)	(102)
Cumulative translation adjustment	(5)	
Accumulated other comprehensive loss	(149)	(102)
Accumulated deficit	(115,891)	(95,336)

Total stockholders' equity	74,363	59,876
Total liabilities and stockholders' equity	\$ 80,093	\$ 73,646

*See accompanying notes.*

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**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Revenues:</b>			
Collaboration revenue	\$ 12,199	\$ 13,782	\$
Grant revenue	2,456	1,030	826
<b>Total revenues</b>	<b>14,655</b>	<b>14,812</b>	<b>826</b>
<b>Operating expenses:</b>			
Research and development	27,887	23,129	13,786
General and administrative	9,258	8,543	4,804
<b>Total operating expenses</b>	<b>37,145</b>	<b>31,672</b>	<b>18,590</b>
<b>Loss from operations</b>	<b>(22,490)</b>	<b>(16,860)</b>	<b>(17,764)</b>
Interest income, net	1,935	889	412
<b>Net loss</b>	<b>(20,555)</b>	<b>(15,971)</b>	<b>(17,352)</b>
Deemed dividend upon issuance of ordinary shares of Dynavax Asia			(633)
<b>Net loss attributable to common stockholders</b>	<b>\$ (20,555)</b>	<b>\$ (15,971)</b>	<b>\$ (17,985)</b>
<b>Basic and diluted net loss per share attributable to common stockholders</b>	<b>\$ (0.79)</b>	<b>\$ (0.75)</b>	<b>\$ (10.04)</b>
<b>Shares used to compute basic and diluted net loss per share attributable to common stockholders</b>	<b>25,914</b>	<b>21,187</b>	<b>1,791</b>

*See accompanying notes.*

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**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS**  
**EQUITY (NET CAPITAL DEFICIENCY)**  
(In thousands, except per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Compensation	Notes Receivable From Stockholders	Accumulated Other Comprehensive Income (Loss)		Stockholders Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount				Deficit		
Balances at December 31, 2002	39,514	\$ 83,635	1,849	\$ 2	\$ 8,423	\$ (2,120)	\$ (714)	\$ 51	\$ (62,013)	\$ (56,371)
Issuance of common stock upon exercise of options at \$0.50 to \$3.00 per share for cash			55		73					73
Interest accrued on notes receivable from stockholders							(40)			(40)
Repayment of notes receivable from stockholders							100			100
Common stock repurchased			(20)		(43)					(43)
Deferred stock compensation					4,309	(4,309)				
Amortization of deferred stock compensation							1,752			1,752
Deemed dividend upon issuance of ordinary shares of Dynavax Asia					633					(633)
Comprehensive loss:										
Change in unrealized loss								(51)		(51)

on marketable securities										
Net loss									(17,352)	(17,352)
Comprehensive loss										(17,403)
Balances at December 31, 2003	39,514	\$ 83,635	1,884	\$ 2	\$ 12,762	\$ (4,677)	\$ (654)	\$	\$ (79,365)	\$ (71,932)
Issuance of common stock upon initial public offering			6,900	7	46,448					46,455
Conversion of preferred stock upon initial public offering	(39,514)	(83,635)	13,712	14	83,621					83,635
Conversion of ordinary shares in Dynavax Asia upon initial public offering			2,111	2	14,731					14,733
Exercise of stock options			7		16					16
Issuance of common stock under Employee Stock Purchase Plan			13		70					70
Interest accrued on notes receivable from stockholders								(37)		(37)
Repayment of notes receivable from stockholders								272		272
Deferred stock compensation					1,426	(1,426)				
Amortization of deferred stock compensation								2,737		2,737
Comprehensive loss:										
Change in unrealized loss on marketable securities								(102)		(102)
Net loss									(15,971)	(15,971)

Comprehensive loss	(16,073)
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Balances at December 31, 2004	\$	24,627	\$ 25	\$ 159,074	\$ (3,366)	\$ (419)	\$ (102)	\$ (95,336)	\$ 59,876
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**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS**  
**EQUITY**  
**(NET CAPITAL DEFICIENCY) (CONTINUED)**  
**(In thousands, except per share amounts)**

	Convertible Preferred Stock  Shares Amount	Common Stock		Deferred Stock Compensation	Notes Receivable From Stockholders	Accumulated		Stockholders Equity (Net Capital Deficiency)
		Par Shares Amount	Additional Paid-In Capital			Other Comprehensive Income Accumulated Deficit	Stockholders Equity (Net Capital Deficiency)	
Balances at December 31, 2004	\$ 24,627	\$ 25	\$ 159,074	\$ (3,366)	\$ (419)	\$ (102)	\$ (95,336)	\$ 59,876
Issuance of common stock upon underwritten public offering	5,720	5	33,132					33,137
Exercise of stock options	113		19					19
Issuance of common stock under Employee Stock Purchase Plan	22		114					114
Interest accrued on notes receivable from stockholders					(16)			(16)
Repayment of notes receivable from stockholders					435			435
Deferred stock compensation			501					501
Amortization of deferred stock compensation				899				899
Comprehensive loss:								
Change in unrealized loss on marketable securities						(42)		(42)



Cumulative translation adjustment						(5)		(5)
Net loss							(20,555)	(20,555)

Comprehensive loss								(20,602)
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Balances at December 31, 2005	\$	30,482	\$	30	\$	192,840	\$	(2,467)	\$	(149)	\$	(115,891)	\$	74,363
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*See accompanying notes.*

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**DYNAVAX TECHNOLOGIES CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Operating activities</b>			
Net loss	\$ (20,555)	\$ (15,971)	\$ (17,352)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	759	536	576
Loss on disposal of property and equipment		18	34
Accretion and amortization on marketable securities	973	361	581
Realized loss on investment	(1)		
Interest accrued on notes receivable from stockholders	(16)	(37)	(40)
Amortization of stock-based compensation expense	1,400	2,737	1,752
Changes in operating assets and liabilities:			
Accounts receivable	2,442	(2,911)	(220)
Prepaid expenses and other current assets	119	26	(705)
Other assets	(10)	(384)	33
Accounts payable	(439)	(19)	14
Accrued liabilities	(530)	1,312	921
Deferred revenues	(7,000)	7,000	
Net cash used in operating activities	(22,858)	(7,332)	(14,406)
<b>Investing activities</b>			
Purchases of marketable securities	(84,014)	(49,637)	(7,022)
Maturities and sales of marketable securities	65,869	5,549	25,000
Purchases of property and equipment	(562)	(1,863)	(138)
Net cash (used in) provided by investing activities	(18,707)	(45,951)	17,840
<b>Financing activities</b>			
Proceeds from issuance of ordinary shares in Dynavax Asia, net of issuance costs			14,733
Proceeds from issuance of common stock, net of issuance costs	33,137	46,455	73
Exercise of stock options	19	16	
Proceeds from employee stock purchase plan	114	70	
Repurchase of common stock			(43)
Repayment of notes receivable from stockholders	435	272	100
Restricted cash		(408)	
Net cash provided by financing activities	33,705	46,405	14,863
Effect of exchange rate on cash and cash equivalents	(5)		

Net (decrease) increase in cash and cash equivalents	(7,865)	(6,878)	18,297
Cash and cash equivalents at beginning of year	16,590	23,468	5,171
Cash and cash equivalents at end of year	\$ 8,725	\$ 16,590	\$ 23,468
<b>Supplemental disclosure of non-cash investing and financing activities</b>			
Lease incentive	\$	\$ 350	\$
Net change in unrealized loss on marketable securities	\$ (42)	\$ (102)	\$ (51)
Change in cumulative translation adjustment	\$ (5)	\$	\$
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	\$
Repurchase of common stock for notes receivable	\$	\$	\$ 43
Interest accrued on notes receivable	\$	\$ 37	\$ 40
Deemed dividend upon issuance of ordinary shares of Dynavax Asia	\$	\$	\$ 633

*See accompanying notes.*

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**DYNAVAX TECHNOLOGIES CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization**

Dynavax Technologies Corporation ( Dynavax or the Company ) is a biopharmaceutical company that discovers, develops, and intends to commercialize innovative products to treat and prevent allergies, infectious diseases, and chronic inflammatory diseases. The Company was originally incorporated in California on August 29, 1996 and reincorporated in Delaware on March 26, 2001.

The Company completed its initial public offering in February 2004 and adjusted shares sold in a one-for-three reverse stock split. The effect of the reverse stock split is reflected in the Consolidated Financial Statements for all periods presented.

**Subsidiaries**

In October 2003, the Company formed Dynavax Asia Pte. Ltd. (Dynavax Asia), a 100% owned subsidiary in Singapore. In October 2003, the Company completed a sale of 15,200,000 ordinary shares in Dynavax Asia, which reduced the Company's ownership in Dynavax Asia from 100% to 50%. The sale raised net proceeds of \$14.7 million, which were recorded as a minority interest liability in the Consolidated Financial Statements as of December 31, 2003. In addition, the Company recorded a deemed dividend of \$0.6 million for the year ended December 31, 2003 on the difference between the estimated fair value of the common stock at the issuance date and the conversion price of the ordinary shares. In connection with the February 2004 initial public offering, the ordinary shares in Dynavax Asia were converted to 2,111,111 shares of common stock and Dynavax Asia returned to being a wholly owned subsidiary.

In December 2004, the Company formed Ryden Therapeutics KK (Ryden), a 100% owned Japan subsidiary, to explore development, commercialization and financing options for ISS-based immunotherapies for cedar tree allergy in Japan.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The Consolidated Financial Statements include the accounts of Dynavax, Dynavax Asia and Ryden. All significant intercompany accounts and transactions have been eliminated. The Company operates in one business segment, which is the discovery and development of biopharmaceutical products.

**Use of Estimates**

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

**Foreign Currency**

The Company considers 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. To date, virtually all operations of Dynavax Asia and Ryden are conducted in the U.S. and, as such, have

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resulted in nominal foreign currency translation adjustments or transaction gains or losses as of December 31, 2005.

**Cash Equivalents and Marketable Securities**

The Company considers 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. The Company has classified its entire investment portfolio as available-for-sale. The Company views its available-for-sale portfolio as available for use in current operations, and accordingly, has 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, the Company has had no declines in fair value that have been identified as other than temporary.

**Fair Value of Financial Instruments**

Carrying amounts of certain of the Company's 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. The Company's policy is to invest its 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. The Company reviews its exposure to accounts receivable and to date has not experienced any losses. The Company does not currently require collateral for any of its trade accounts receivable. As of December 31, 2005, our accounts receivable were derived primarily from governmental grants. As of December 31, 2004, the majority of our accounts receivable were derived from a collaboration agreement with UCB Farchim, SA (UCB) which ended in March 2005. The Company collected all receivables due from UCB that remained outstanding at December 31, 2004.

The Company's 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 the Company's products will receive any of these required approvals. The denial or delay of such approvals would have a material adverse impact on the Company's consolidated financial position and results of operations.

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The Company relies on a single contract manufacturer to produce material for certain of its clinical trials. While the Company has identified several additional manufacturers with whom it could contract for the manufacture of material, the Company has not entered into agreements with them and loss of its current supplier could delay development or commercialization of the Company's product candidates. To date, the Company has manufactured only small quantities of material for research purposes.

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

### **Property and Equipment**

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets: three years for computer equipment and furniture, and five years for laboratory equipment. Leasehold improvements are amortized using the straight-line method over the remaining life of the initial lease term or the estimated useful lives of the assets, typically five years, whichever is shorter. Repair and maintenance costs are charged to expense as incurred.

### **Long-lived Assets**

The Company identifies and records 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 exceed the projected discounted future net cash flows associated with the assets. None of these events or circumstances has occurred with respect to the Company's long-lived assets, which consist mainly of lab equipment.

### **Revenue Recognition**

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. We recognize collaboration, upfront and other revenue based on the terms specified in the agreements, generally as work is performed or approximating a straight-line basis over the period of the collaboration. Any amounts received in advance of performance are recorded as deferred revenue and amortized 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 is nonrefundable.

Revenues related to government and private agency grants are recognized as the related research expenses are incurred. 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.

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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.

**Stock-Based Compensation**

The Company has adopted the pro forma disclosure requirements of SFAS 123, *Accounting for Stock-Based Compensation* as amended by SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. As permitted under SFAS 123, we continue to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by APB 25 and its interpretations. Under APB 25, compensation expense is based on the difference, if any, between the estimated fair value of our common stock and the option exercise price on the date of grant.

The following table illustrates the pro forma effect on our net loss and net loss per share as if we had applied the fair value recognition provisions of SFAS 123 to employee stock compensation (in thousands, except per share amounts):

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss attributable to common stockholders, as reported	\$ (20,555)	\$ (15,971)	\$ (17,985)
Add: Stock-based employee compensation expense included in net loss	1,410	2,170	1,752
Less: Stock-based employee compensation expense determined under the fair value based method	(2,785)	(2,816)	(1,996)
Net loss attributable to common stockholders, pro forma	\$ (21,930)	\$ (16,617)	\$ (18,229)
<b>Net loss per share attributable to common stockholders:</b>			
Basic and diluted, as reported	\$ (0.79)	\$ (0.75)	\$ (10.04)
Basic and diluted, pro forma	\$ (0.84)	\$ (0.78)	\$ (10.18)

Such pro forma disclosure may not be representative of future stock-based compensation expense because such options vest over several years and additional grants may be made each year.

The estimated fair value of each option and employee purchase right is estimated on the date of grant using the Black-Scholes option-pricing model, assuming no expected dividends and the following weighted-average assumptions:

	<b>Employee Stock Options</b>			<b>Employee Stock Purchase Plan</b>	
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2005</b>	<b>2004</b>
Weighted-average fair value					

	\$3.68	\$5.04	\$6.68	\$3.03	\$7.50
Risk-free interest rate					
	3.5% to 4.4%	2.3% to 3.5%	2.4% to 2.9%	2.9%	2.0%
Expected life (in years)					
	4	4	4	1.24	0.5
Volatility					
	0.7	0.7	1.0	0.7	0.7

**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. The Company includes unrealized holding gains



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and losses on marketable securities and cumulative translation adjustments in accumulated other comprehensive loss.

**Income Taxes**

We account for income taxes using the asset and 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 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 the Company has incurred losses to date.

**Recent Accounting Pronouncements**

On March 29, 2005, the SEC published Staff Accounting Bulletin (SAB) No. 107 regarding the interaction between Financial Accounting Standard (SFAS) No. 123R (revised 2004), Share-Based Payment and certain SEC rules and regulations. On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, which requires all share-based payments to employees to be recognized in the statement of operations. Pro forma disclosure is no longer an alternative. SFAS 123R supersedes Accounting Principles Board (APB) No. 25, Accounting for Stock Issued to Employees, and amends SFAS 95, Statement of Cash Flows.

SFAS 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date. Under SFAS 123R, share-based payments to employees result in a cost that will be measured at fair value on the awards grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised.

We will adopt SFAS 123R as of January 1, 2006. We intend to use the modified prospective transition method of adoption, which requires that we recognize compensation expense on awards that are modified, repurchased or cancelled after the adoption date. When measuring fair value, we plan to continue to use the Black-Scholes option-pricing model. We expect the adoption of SFAS 123R to have a significant negative impact on our results of operations in fiscal 2006 and thereafter, primarily dependent on levels of share-based payments granted in the future as well as our assumptions used to determine fair value. We estimated that the application of SFAS 123R on the outstanding and unvested options at December 31, 2005 (excluding the assumption of any new options granted thereafter) would approximate the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share above.

**Table of Contents****3. Marketable Securities**

The following is a summary of available-for-sale securities as of December 31, 2005 and 2004 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>December 31, 2005:</b>				
Corporate debt securities	\$ 66,529	\$	\$ (144)	\$ 66,385
<b>December 31, 2004:</b>				
U.S. Treasury notes and other U.S. government agency securities	\$ 3,489	\$ 1	\$ (1)	\$ 3,489
Certificates of deposit and money market funds	999			999
Corporate debt securities	44,868	2	(104)	44,766
<b>Total</b>	<b>\$ 49,356</b>	<b>\$ 3</b>	<b>\$ (105)</b>	<b>\$ 49,254</b>

There were no realized gains from sales of marketable securities for the years ended December 31, 2005 and 2004. Realized losses from the sale of marketable securities were nominal in 2005 and zero in 2004. As of December 31, 2005 and 2004, 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, 2005, our marketable securities had the following maturities (in thousands):

Maturities in:	Amortized Cost	Estimated Fair Value
2006	\$ 66,529	\$ 66,385
Total	\$ 66,529	\$ 66,385

**4. Property and Equipment**

Property and equipment consist of the following (in thousands):

	December 31,	
	2005	2004
Laboratory equipment	\$ 2,638	\$ 2,327
Computer and equipment	797	661
Furniture and fixtures	755	737
Leasehold improvements	1,257	1,220
	5,447	4,945
Less accumulated depreciation and amortization	(3,250)	(2,480)
	<b>\$ 2,197</b>	<b>\$ 2,465</b>

Depreciation and amortization expense on property and equipment was \$0.8 million, \$0.5 million and \$0.6 million for the years ended December 31, 2005, 2004, and 2003, respectively.

**Table of Contents****5. Current Accrued Liabilities**

Current accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Payroll and related expenses	\$ 1,735	\$ 1,093
Legal expenses	273	422
Third party scientific research expense	1,354	1,607
Other accrued liabilities	479	1,249
	<b>\$ 3,841</b>	<b>\$ 4,371</b>

**6. Commitments and Contingencies**

The Company leases its facility under an operating lease that expires in September 2014. The lease can be terminated at no cost to the Company in September 2009 but otherwise extends automatically until September 2014.

Our facility lease agreement 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 lease agreement provides 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 Sheet as of December 31, 2004 and 2005. The lease incentive will be amortized as an offset to rent expense over the estimated initial lease term, through September 2009. Total net rent expense related to this operating lease for the years ended December 31, 2005, 2004 and 2003, was \$1.4 million, \$1.4 million and \$0.6 million, respectively. Deferred rent was \$0.1 million as of December 31, 2005.

We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to the Company of \$0.3 million in 2005 and \$0.4 million annually thereafter through 2007. This sublease agreement includes an option for early termination in August 2006 but otherwise extends automatically until August 2007.

Future minimum payments under the non-cancelable portion of our operating lease at December 31, 2005, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2006	\$ 1,704
2007	1,755
2008	1,808
2009	1,231
	<b>\$ 6,498</b>

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our property lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2005 and is collateralized by a certificate of deposit which has been included in restricted cash in the Consolidated Balance Sheets as of December 31, 2005 and 2004. Under the terms of the lease agreement, 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.



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We rely on research institutions and contract research organizations that conduct and manage clinical trials on our behalf. As of December 31, 2005, under the terms of our agreements with a contract research organization (CRO) and clinical investigator, we are obligated to make future payments as services are provided of approximately \$27 million through 2008. These agreements are terminable by us upon written notice to the CRO. 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.

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officers or directors are or were serving at the Company's request in such capacity. The term of the indemnification period is for each officer or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2005.

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2005.

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

### *UCB Farchim, S.A.*

In March 2005, the Company agreed to end its collaboration with UCB Farchim, S.A. (UCB) and regained full rights to its allergy program. During the second quarter of 2005, the Company 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 the Company had no ongoing obligations under the collaboration. Collaboration revenue from UCB amounted to \$12.2 million and \$13.8 million during the years ended December 31, 2005 and 2004, respectively.

### *University of California*

The Company entered into a series of exclusive license agreements with the Regents of the University of California (UC) in March 1997 and October 1998. These agreements provide the Company with certain technology and related patent rights and materials. Under the terms of the agreements, the Company pays annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. The agreements will expire on either the expiration date of the last-to-expire patent licensed under the agreements or the date upon which the last patent application licensed under the agreements is abandoned.

In connection with these license agreements, the Company incurred license fees of \$20,000 in each of the fiscal years 2005, 2004 and 2003 which was recorded as research and development expense, and the Company incurred patent expenses of \$0.5 million, \$0.5 million, and \$0.2 million in the years ended December 31, 2005, 2004, and 2003, respectively, which was recorded as general and administrative expense. As partial consideration for the technology licenses, the Company also incurred a \$0.4 million one-time charge due upon the closing of the Company's initial public offering in the first quarter of 2004, which was recorded as research and development expense. Additionally, as partial consideration for the

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technology licenses, the Company paid \$0.2 million to UC related to the collaboration with UCB. During the year ended December 31, 2005, in conjunction with the ending of the UCB collaboration, the Company incurred \$0.1 million in research and development expense from the accelerated amortization of the prepaid technology license fee.

*BioSeek, Inc.*

In June 2003, the Company entered into a development collaboration agreement with BioSeek, Inc. to analyze and characterize the activity of certain compounds using BioSeek's technology with the objective of advancing the development of such compounds. Under this agreement, the Company will make various payments to BioSeek based on the success and timing of the Company's signing of a third party partnering agreement where the Company grants to the third party, directly or indirectly, any right or option to market, sell, distribute or otherwise commercialize a thiazolopyrimidine (TZP) product in any geographic territory. During the year ended December 31, 2005, the Company paid BioSeek \$0.3 million associated with the achievement of a development milestone.

*Other Agreements*

In 2003, the Company was awarded government grants totaling \$8.4 million to be received over as long as three and one-half years, assuming annual review criteria are met, to fund research and development of certain biodefense programs. Revenue associated with these grants is recognized as the related expenses are incurred. During 2005, the indirect cost rate associated with these grants was approved by the National Institutes of Health. As a result, grant revenue for the year ended December 31, 2005 included a one-time increase of \$0.5 million, reflecting the adjustment under the government grant awards from the previously utilized minimum cost overhead rate allowable to the final approved rate.

In 2004, the Company was 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. For the year ended December 31, 2005, the Company recognized revenue of approximately \$0.2 million associated with the lupus grant.

**8. Net Loss Per Share**

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders 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 the Company, preferred stock, options and warrants are considered to be potentially dilutive common shares

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and are only included in the calculation of diluted net loss per share attributable to common stockholders when their effect is dilutive.

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Historical (in thousands, except per share amounts):</b>			
Numerator:			
Net loss attributable to common stockholders	\$ (20,555)	\$ (15,971)	\$ (17,985)
Denominator:			
Weighted-average common shares outstanding	25,915	21,200	1,849
Less: Weighted-average unvested common shares subject to repurchase	(1)	(13)	(58)
Denominator for basic and diluted net loss per share attributable to common stockholders	25,914	21,187	1,791
Basic and diluted net loss per share attributable to common stockholders	\$ (0.79)	\$ (0.75)	\$ (10.04)
<b>Historical outstanding dilutive securities not included in diluted net loss per share attributable to common stockholders calculation (in thousands):</b>			
Preferred stock			15,823
Options to purchase common stock	2,579	1,828	1,334
Warrants	84	84	84
	2,663	1,912	17,241

**9. 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 the Company's initial public offering. The amendment increased the Company's authorized common stock to 100,000,000 shares and decreased authorized preferred stock to 5,000,000 shares.

In February 2004, the Company sold a total of 6,900,000 shares of its common stock, after adjusting for a one-for-three reverse stock split, in an underwritten initial public offering, raising net proceeds of approximately \$46.5 million. As a result of the initial public offering, all outstanding shares of convertible preferred stock converted to 13,712,128 shares of common stock. Also in connection with the initial public offering, the ordinary shares in Dynavax Asia were converted to 2,111,111 shares of common stock and Dynavax Asia became a wholly owned subsidiary. In the fourth quarter of 2005, the Company sold a total of 5,720,000 shares of its common stock in an underwritten public offering, raising net proceeds of approximately \$33.1 million.

**Warrants**

In August 2002, in connection with the closing of the Series D Preferred Stock financing, the Company issued a warrant to its placement agent valued at approximately \$0.3 million using the Black-Scholes option-pricing model. This amount was initially recorded in convertible preferred stock as an issuance cost and subsequently converted to 84,411 shares of common stock upon the closing of our initial public offering. The warrant 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, 2005.

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**Stock Option Plans**

In January 1997, the Company 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 Company 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, the Company 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, 2005, 3,900,000 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 the Company s common stock or capital structure. During the year ended December 31, 2005, the Company issued 140,825 shares of common stock resulting from option exercises, of which 27,817 shares were surrendered to the Company in lieu of cash payment for the option exercise.

Also in January 2004, the Board of Directors and stockholders adopted the 2004 Non-employee Director Option Program and 2004 Director Cash Compensation Program which was revised in April 2005. The plan generally provides that each director receive an initial option grant, subsequent annual grants at the stockholders meeting each year thereafter, an annual retainer, and cash compensation for each board meeting attended. Certain of the Company s directors and their affiliates beneficially owned or controlled approximately 14% of our outstanding common stock as of December 31, 2005. For the year ended December 31, 2005, the Company incurred approximately \$0.1 million in general and administrative expense associated with payments to these directors under the compensation plan.

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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, 2002	22,840	691,185	\$ 2.48
Options authorized	1,000,000		
Options granted	(828,488)	828,488	\$ 2.34
Options exercised		(54,699)	\$ 1.34
Options canceled	130,993	(130,993)	\$ 2.38
Shares repurchased	19,715		\$ 2.21
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	(915,550)	915,550	\$ 6.53
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	2,851,668	2,578,797	\$ 4.42

The following summarizes options outstanding and exercisable under our stock option plans as of December 31, 2005:

<b>Options Outstanding</b>			<b>Options Exercisable</b>		
<b>Range of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Weighted-Average Remaining Contractual Life (years)</b>	<b>Weighted-Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted-Average Exercise Price</b>
\$0.60-1.20	29,254	3.8	\$ 1.03	29,254	\$ 1.03
\$1.50	374,050	7.2	\$ 1.50	374,050	\$ 1.50
\$3.00	959,805	7.3	\$ 3.00	959,805	\$ 3.00
\$3.66-4.58	269,906	9.3	\$ 4.21	27,683	\$ 4.58

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\$4.63-6.65	261,900	9.2	\$	6.27	49,026	\$	6.32
\$7.00-7.32	334,950	9.0	\$	7.24	37,476	\$	7.21
\$7.49	275,000	9.1	\$	7.49	63,019	\$	7.49
\$7.99	34,600	8.2	\$	7.99	12,782	\$	7.99
\$9.05	28,000	8.4	\$	9.05	11,689	\$	9.05
\$12.00	11,332	5.3	\$	12.00	11,332	\$	12.00
\$0.60-12.00	2,578,797	8.1	\$	4.42	1,576,116	\$	3.17

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The following summarizes options outstanding and exercisable under our stock option plans as of December 31, 2004:

Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$0.60-1.20	29,586	4.8	\$ 1.02	29,586	\$ 1.02
\$1.50	511,547	8.1	\$ 1.50	511,547	\$ 1.50
\$3.00	965,699	8.3	\$ 3.00	965,699	\$ 3.00
\$4.58-5.65	99,000	9.7	\$ 4.69		
\$5.90	10,000	9.8	\$ 5.90		
\$6.45	113,250	9.7	\$ 6.45	5,308	\$ 6.45
\$6.65	15,000	9.9	\$ 6.65		
\$7.99	37,550	9.2	\$ 7.99	4,535	\$ 7.99
\$9.05	35,350	9.4	\$ 9.05		
\$12.00	11,332	6.3	\$ 12.00	11,332	\$ 12.00
\$0.60-12.00	1,828,314	8.4	\$ 3.17	1,528,007	\$ 2.55

Employee and director stock-based compensation expense and non-employee stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,		
	2005	2004	2003
Employees and directors stock-based compensation expense	\$ 1,410	\$ 2,170	\$ 1,752
Non-employees stock-based compensation expense	(10)	567	
<b>Total</b>	<b>\$ 1,400</b>	<b>\$ 2,737</b>	<b>\$ 1,752</b>

**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, 2005, 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 the Company's common stock or capital structure. To date, employees acquired 34,692 shares of our common stock under the Purchase Plan.

At December 31, 2005, 461,308 shares of our common stock remained available for future purchases.

**10. Employee Benefit Plan**

Effective September 1997, the Company 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. The Company may, at its discretion, contribute for the benefit of eligible employees. To date, the Company has not contributed to the 401(k) Plan.

**Table of Contents****11. Related Party Transactions**

From September 2000 through June 2001, the Company loaned \$0.8 million to certain key employees and officers for the exercise of incentive stock options. These full recourse notes, which were collateralized by shares of common stock held by the employees and which accrued interest at rates ranging from 5.02% to 6.22%, were paid in full by December 31, 2005.

In December 1998, the Company entered into a research agreement with the Regents of the University of California, or UC, on behalf of the University of California, San Diego, under which the Company agreed to fund a research project aimed at uncovering novel applications for ISS. The university-nominated representative on the evaluation committee created to oversee aspects of this agreement is Dr. Dennis Carson, a member of the Company's Board of Directors and a holder of 376,119 shares of the Company's common stock as of December 31, 2005. Dr. Carson also received payment of \$11,667, \$35,000 and \$35,000 in fiscal 2005, 2004 and 2003, respectively, for consulting services provided to the Company.

**12. Income Taxes**

Worldwide loss before provision for income taxes consists of the following (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
U.S.	\$ (12,331)	\$ (10,216)	\$ (16,461)
Non U.S.	(8,224)	(5,755)	(891)
<b>Total</b>	<b>\$ (20,555)</b>	<b>\$ (15,971)</b>	<b>\$ (17,352)</b>

No income tax expense was recorded for the years ended December 31, 2005, 2004 and 2003 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>2005</b>	<b>2004</b>	<b>2003</b>
Income tax benefit at federal statutory rate	\$ (6,989)	\$ (5,430)	\$ (5,900)
State tax	(1,137)	(758)	(895)
Unbenefited foreign losses	4,752		303
Tax credits	(502)	(282)	(537)
Deferred compensation charges	342	931	596
Change in valuation allowance	2,872	5,185	6,548
Other	662	354	(115)
	\$	\$	\$

Deferred tax assets and liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Deferred tax assets:</b>		

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Net operating loss carry forwards	\$ 24,312	\$ 17,339
Research tax credit carry forwards	2,093	1,587
Accruals and reserves	416	4,695
Capitalized research costs	11,012	11,020
Other	(88)	232
Total deferred tax assets	37,745	34,873
Less valuation allowance	(37,745)	(34,873)
	\$	\$



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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 all deferred tax assets at December 31, 2005 and 2004. The valuation allowance increased by \$2.9 million, \$5.2 million and \$6.5 million during the years ended December 31, 2005, 2004 and 2003, respectively.

As of December 31, 2005, the Company had federal net operating loss carryforwards of approximately \$61 million and federal research and development tax credits of approximately \$1.2 million, which expire at various dates from 2011 through 2025 if not utilized.

As of December 31, 2005, the Company had California state net operating loss carryforwards of approximately \$61.3 million, which expire at various dates from 2006 through 2015, and California state research and development tax credits of approximately \$1.3 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.

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

	Year Ended December 31, 2005				Year Ended December 31, 2004			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 12,698	\$ 953	\$ 404	\$ 600	\$ 3,205	\$ 5,492	\$ 3,660	\$ 2,455
Net income (loss) attributable to common stockholders(1)	\$ 5,070	\$ (8,579)	\$ (8,284)	\$ (8,762)	\$ (3,866)	\$ (2,909)	\$ (4,033)	\$ (5,163)
Basic net earnings (loss) per share attributable to common stockholders(1)	\$ 0.21	\$ (0.35)	\$ (0.33)	\$ (0.30)	\$ (0.36)	\$ (0.12)	\$ (0.16)	\$ (0.21)
Diluted net earnings (loss) per share attributable to common stockholders(1)	\$ 0.20	\$ (0.35)	\$ (0.33)	\$ (0.30)	\$ (0.36)	\$ (0.12)	\$ (0.16)	\$ (0.21)
Weighted-average shares used in computing basic net loss per share attributable to common stockholders(2)	24,722	24,745	24,751	29,398	10,847	24,594	24,609	24,622
Weighted-average shares used in computing diluted net loss per share attributable to common stockholders(2)	25,580	24,745	24,751	29,398	10,847	24,594	24,609	24,622

(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 7.

- (2) Our initial public offering occurred in February 2004. The weighted-average shares increased from the first to the second quarter of 2004 due to the increase in the number of days that the common stock was outstanding. The weighted-average shares increased from the third to the fourth quarter of 2005 due to the follow on equity offering that occurred in the fourth quarter of 2005.

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**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, 2005.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included on or about page 48 of this Annual Report on Form 10-K.

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

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

**ITEM 9B. OTHER INFORMATION**

None.

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**PART III**

**ITEM 10. DIRECTORS AND OFFICERS OF THE REGISTRANT**

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 the Company's Definitive Proxy Statement in connection with the 2006 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, 2005.

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: Jane M. Green, Ph.D., Vice President, Corporate Communications, 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 the Company's 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**

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.

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**PART IV**

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

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

**1. Financial Statements**

- Report of Independent Registered Public Accounting Firm 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

**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*	Restated Certificate of Incorporation
3.2*	Amended and Restated Bylaws
4.1*	Specimen Stock Certificate
10.1*	Form of Indemnification Agreement between Dynavax Technologies Corporation and each of its executive officers and directors
10.2*	1997 Equity Incentive Plan, as amended
10.3*	2004 Stock Incentive Plan
10.4*	2004 Employee Stock Purchase Plan
10.5*	Development Collaboration Agreement, dated June 10, 2003, between Dynavax Technologies Corporation and BioSeek, Inc.
10.6*	License and Supply Agreement, dated October 28, 2003, between Dynavax Technologies Corporation and Berna Biotech AG
10.7*	Exclusive License Agreement, dated March 26, 1997, between Dynavax Technologies Corporation and the Regents of the University of California, for Method, Composition and Devices for Administration of Naked Nucleotides which Express Biologically Active Peptides and Immunostimulatory Oligonucleotide Conjugates, including three amendments thereof.
10.8*	Exclusive License Agreement, dated October 2, 1998, between Dynavax Technologies Corporation and the Regents of the University of California, for Compounds for Inhibition of Ceramide-Mediated Signal Transduction and New Anti-Inflammatory Inhibitors: Inhibitors of Stress Activated Protein Kinase Pathways, including one amendment thereof.



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10.9*	Management Continuity Agreement, dated as of October 15,2003, between Dynavax Technologies Corporation and Dino Dina
10.10*	Management Continuity Agreement, dated as of September 2,2003, between Dynavax Technologies Corporation and Daniel Levitt
10.11*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and William J. Dawson
10.12*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Stephen Tuck
10.13*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Robert Lee Coffman
10.14*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Gary Van Nest
10.15*	Lease, dated as of January 7, 2004, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.16*	License and Development Agreement, dated February 5, 2004,between Dynavax Technologies Corporation and UCB Farchim, SA
10.17**	Management Continuity and Severance Agreement, dated as of August 27, 2004, between Dynavax Technologies Corporation and Timothy Henn
10.18**	Management Continuity and Severance Agreement, dated as of January 4, 2005, between Dynavax Technologies Corporation and Deborah A. Smeltzer
21.1***	Subsidiaries of Dynavax Technologies Corporation
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

\* Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-109965) and amendments thereto

\*\* Incorporated by reference to our Reports on Form 8-K, dated August 23, 2004 and January 5, 2005

\*\*\* Previously filed with our Annual Report on Form 10-K filed on March 16, 2006

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



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**SIGNATURES**

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

DYNAVAX TECHNOLOGIES  
CORPORATION

By: /s/ Dino Dina, M.D.  
Dino Dina, M.D.  
President, Chief Executive Officer and  
Director  
(Principal Executive Officer)

Date: April 7, 2006

By: /s/ Deborah A. Smeltzer  
Deborah A. Smeltzer  
Vice President, Operations and  
Chief Financial Officer  
(Principal Financial Officer)

Date: April 7, 2006

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

Date: April 7, 2006

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Dino Dina, M.D. Dino Dina, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	April 7, 2006
/s/ Deborah a. Smeltzer Deborah A. Smeltzer	Vice President, Operations and Chief Financial Officer (Principal Financial Officer)	April 7, 2006
/s/ Timothy G. Henn Timothy G. Henn	Vice President, Finance & Administration and Chief Accounting Officer (Principal Accounting Officer)	April 7, 2006
/s/ Arnold Oronsky, PH.D.*	Chairman of the Board	April 7, 2006

Arnold Oronsky, Ph.D.

/s/ Nancy L. Buc\*

Director

April 7, 2006

Nancy L. Buc

/s/ Dennis Carson, M.D.\*

Director

April 7, 2006

Dennis Carson, M.D.

/s/ Daniel S. Janney\*

Director

April 7, 2006

Daniel S. Janney

/s/ Jan Leschly\*

Director

April 7, 2006

Jan Leschly

/s/ Denise M. Gilbert, Ph.D.\*

Director

April 7, 2006

Denise M. Gilbert, Ph.D.

/s/ Stanley A. Plotkin, M.D.\*

Director

April 7, 2006

Stanley A. Plotkin, M.D.

By: \* /s/ Deborah A. Smeltzer

Deborah A. Smeltzer

Attorney-in-Fact

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