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

# Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2004**

**or**

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

**For the transition period from to .**

**Commission file number: 000-24647**

# Dynavax Technologies Corporation

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

| **Delaware** | **33-0728374** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(IRS Employer Identification No.)* |

**2929 Seventh Street, Suite 100**
**Berkeley, CA 94710-2753**
**(510) 848-5100**
*(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)*

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

| **Title of Each Class:** | **Name of Each Exchange on Which Registered:** |
|---|---|
| None | None |

**Securities Registered Pursuant to Section 12(g) of the Act:**
**Common Stock, par value $0.001 per share**
***(Title of Class)***

Indicate by check mark 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 o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes o 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, 2004 as reported on the Nasdaq National Market, was approximately $99,932,028. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2005, registrant had outstanding 24,745,201 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the registrant's 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

## INDEX

## DYNAVAX TECHNOLOGIES CORPORATION

## 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, 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 variations or 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", "we" or "us") 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 enhance the ability of the immune system to fight disease and control chronic inflammation.

Our most advanced clinical programs are based on our ISS technology and include:

- *AIC for Ragweed Allergy.* We have developed a novel injectable product candidate to treat ragweed allergy that we call AIC. AIC is an immunotherapeutic intervention for ragweed allergy, the most common seasonal allergy in North America. Unlike existing products that treat chronic ragweed allergy symptoms, our product candidate targets the underlying cause of ragweed-induced seasonal allergic rhinitis. AIC has completed Phase II trials, and is currently completing a two-year Phase II/III clinical trial. At the end of 2004, we reported that the one-year interim analysis of this Phase II/ III trial showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season. The interim analysis indicated that AIC was safely administered and systemic adverse reactions were similar between the AIC and control arms. We intend to complete the Phase II/ III clinical trial as planned. We

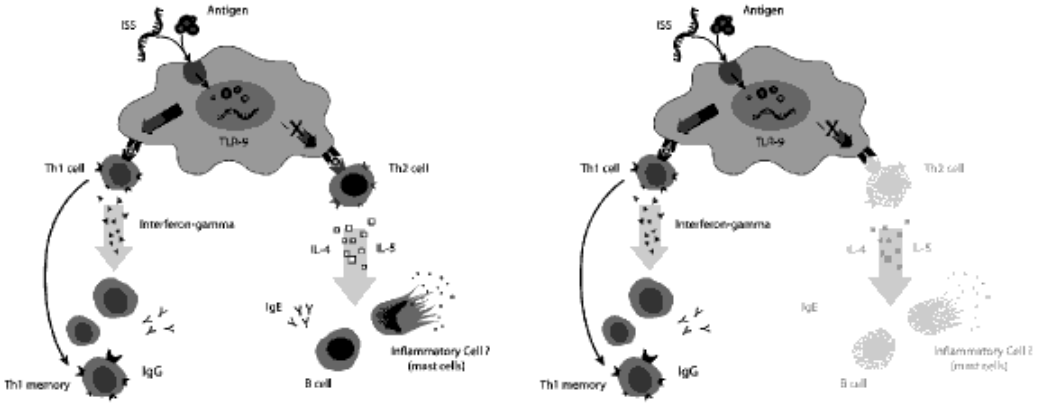
anticipate initiating a supportive Phase III clinical trial in a pediatric indication in the first half of 2005. Pending the outcome of discussions with the US Food and Drug Administration (FDA) in 2005 and the results of the Phase II/III study, we plan to initiate a pivotal Phase III clinical program in early 2006.

- *Hepatitis B Prophylaxis.* A Phase II program in adolescents conducted in Canada has been completed. In these trials our hepatitis B vaccine induced more rapid immunity with fewer immunizations than currently available vaccines. Based on these results, we believe that our hepatitis B vaccine has the potential to increase compliance and decrease the spread of the disease. Results from Phase I and Phase II trials demonstrated that our hepatitis B vaccine was well tolerated and conferred protective hepatitis B antibody levels following two injections over a two-month period. A Phase II/ III trial in subjects who are less responsive to conventional vaccine is currently underway in Singapore. Results from an interim analysis of the Phase II/ III trial showed that our vaccine demonstrated statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B™ vaccine. We anticipate initiating Phase III trials in Canada, Europe and Asia in 2005, pending the outcome of the current trial. Our intention is to initially commercialize our hepatitis B vaccine outside of the United States.
- *Asthma.* We have an inhaled therapeutic product candidate for treatment of asthma, which has completed a Phase IIa trial in Canada. Unlike current treatments for asthma, which require chronic use, our product may provide long-term relief following a single course of administration. Results from our Phase I trial demonstrated that our product candidate was well tolerated in healthy volunteers and may have the potential to suppress both clinical symptoms and the underlying inflammatory response associated with asthma. Results from a Phase IIa asthma challenge study confirmed the safety of inhaled immunostimulatory sequences in asthmatic patients, and showed substantial and statistically significant pharmacological activity, based upon the induction of genes associated with a reprogrammed immune response. After allergen challenges at weeks two and four, no significant changes in pulmonary function were observed between placebo and treated groups. We anticipate initiating a Phase II study in asthma in late 2005.

We have preclinical programs focused on other allergies, chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies. These include an early-stage research program focused on a new class of oligonucleotides called immunoregulatory sequence (IRS) technology, as well as a program focused on developing orally available small molecules in the thiazolopyrimidine (TZP) class, to treat autoimmune disease.

**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 leads to the production of specific cytokines, including interferon-alpha, interferon-gamma and interleukin 12, or IL-12, as well as the generation of killer T cells, a specialized immune cell. These cytokines and killer T cells are believed to be the body's most potent anti-infective weapons. In addition, protective IgG antibodies are generated that also help rid the body of foreign antigens and allergens. Once a population of Th1 cells specific to a particular antigen or allergen is produced, it persists for a long period of time in the form of memory Th1 cells, even if the antigen or allergen target is eliminated. If another infection by the same pathogen occurs, the immune system is able to react more quickly and powerfully to the infection, because the memory Th1 cells can reproduce immediately. When the Th1 response to an infection is insufficient, chronic disease can result. When the Th1 response is inappropriate, diseases such as rheumatoid arthritis can result, in part from elevated levels of Th1 cytokines.

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

**ISS and the Immune System**

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

**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 700 people without observing any serious, drug-related, adverse events. We have demonstrated the clinical benefit of AIC 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**

***AIC for Ragweed Allergy and its Benefits***

Our lead anti-allergy product, AIC, consists of 1018 ISS linked to the purified major allergen of ragweed, called Amb a 1. AIC targets 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 and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy. Moreover, this treatment reprograms 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 AIC. AIC has been tested in fourteen clinical trials in the U.S., France and Canada, and more than 3,000 AIC injections have been administered in more than 500 patients. In these trials, AIC was shown to be safe and well tolerated, to provide measurable improvements in allergy symptoms and to reduce medication use. We are conducting a two-year multi-site Phase II/ III trial in the U.S. to evaluate the efficacy of AIC. We have 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 AIC. Some patients will receive two additional booster shots of AIC 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. At the end of 2004, we reported that the one-year interim analysis of this Phase II/ III trial showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season. The interim analysis indicated that AIC was safely administered and systemic adverse reactions were similar between the AIC and control arms. We intend to complete the two-year clinical trial as planned, a decision that was endorsed by an independent Drug Safety Monitoring Board. Pending the outcome of discussions with the US Food and Drug Administration (FDA) in 2005 and the results of the Phase II/III study, we will determine the design, target populations and timing of initiating a pivotal Phase III clinical program in early 2006. In addition, Dynavax will discuss with the FDA plans to initiate a supportive Phase III trial in a pediatric indication in 2005.

***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 AIC 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.

***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 AIC 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 AIC. For example, the major grass allergen, Lol p 1, and the major cedar tree allergen, Cry j 1, can be linked to ISS. As with AIC, 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.

AIC 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 AIC. 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 are developing a peanut allergy product candidate that consists of ISS linked to a major peanut allergen, Ara h 2. We have demonstrated in mice that peanut allergen linked to ISS induces much higher levels of Th1-induced IgG antibodies and lower levels of IgE than natural peanut allergen. ISS-linked Ara h 2 also induces much higher levels of interferon-gamma and much lower levels of IL-5 than unmodified Ara h 2 in mice. Immunization with our product candidate has also been shown to protect peanut allergic animals from anaphylaxis and death following exposure to peanut allergen. In addition, we have demonstrated that ISS-linked Ara h 2 has significantly reduced allergic response as measured by in vitro histamine release assays using blood cells from peanut allergic patients.

***Commercial Opportunity***

Peanut allergy accounts for the majority of severe food-related allergic reactions. Approximately 1.5 million people in the U.S. have a potentially life-threatening allergy to peanuts and the incidence is growing rapidly. There are an estimated 100 to 200 deaths from severe peanut allergy in the U.S. each year.

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

There are currently no products available that prevent peanut allergy. People allergic to peanuts must take extreme avoidance measures, carefully monitoring their exposure to peanuts and peanut byproducts. Emergency treatment 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 February 2004, Dynavax and UCB Farchim, S.A., a subsidiary of UCB, S.A., or UCB, established a strategic partnering agreement for the development and commercialization of seasonal allergy products. In March 2005, Dynavax and UCB agreed to end their collaboration. Under the terms of the agreement, UCB will return all rights to the allergy program to Dynavax and the current ongoing Phase II/ III clinical trial of our AIC immunotherapy for ragweed allergy will be completed as planned. Dynavax will assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to AIC and for preclinical development programs in grass and in peanut allergy.

**Hepatitis B Products**

**Hepatitis B Prevention**

***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. Our vaccine candidate is composed of hepatitis B surface antigen combined with 1018 ISS and, unlike conventional vaccines, appears to require only two immunizations over two months to achieve protective hepatitis B antibody responses. In clinical trials we have been able to reduce both the time and number of injections required to reach protective hepatitis B antibody responses because of the potent immune-enhancing properties of ISS, which we believe may lead to protective hepatitis B antibody responses after one or two immunizations and thus provide superior field efficacy as compared to current hepatitis B vaccines.

***Clinical Status***

Results from Phase I and from Phase II trials showed that our vaccine candidate was well tolerated and induced more rapid immunity with fewer immunizations than Engerix-B®, 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 are also conducting a Phase II/ III trial in Singapore to evaluate the efficacy of our vaccine in older subjects (ages 40-70 years) who have a diminished ability to respond to current commercial vaccines. Data from an interim analysis of the Company's hepatitis B virus (HBV) vaccine Phase II/ III clinical trial showed statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B®. The primary endpoint of the ongoing Phase II/ III trial is seroprotection four weeks after administration of the third dose. Pending the outcome of the current trial, we intend to pursue a broad Phase III clinical program in multiple age groups in mid-2005 with primary endpoints of protective hepatitis B antibody responses after each injection.

***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 exceed $1.0 billion globally.

We are pursuing a diversified development and commercialization strategy for its hepatitis B vaccine. Our clinical strategy is to determine the effect of a two-dose regimen in adolescents and young adults as well as a three-dose regimen in older patients who are typically less responsive to conventional vaccines. The vaccine may also be developed for the perinatal immunization of infants born to infected mothers, a particularly high-risk segment where transmission rates exceed 90%. We also plan to develop our hepatitis B vaccine for high-risk populations that may include the pre-hemodialysis market segment.

We plan to commercialize our hepatitis B vaccine initially in various markets outside the U.S. We are also evaluating the potential of developing more potent second-generation vaccines that may offer advantages particularly for high-risk populations.

***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 overweight or who smoke. Additionally, there is an inversely proportional relationship between age and the degree to which current vaccines confer protective hepatitis B antibody responses: the older you are, the less effective current vaccines are. Compliance with the immunization regimen is also a significant issue, as many patients fail to receive all three doses. According to a survey of U.S. adolescents and adults published by the Centers for Disease Control, of those who received

the first dose of vaccine, only 53% received the second dose of vaccine and only 30% received the third. We believe that compliance rates in other countries are similar or worse. For healthy young adults, protective hepatitis B antibody responses after the first dose are reported to be between 10% and 12% and improve to only 38% to 56% after the second dose. Consequently, an unacceptably large number of individuals who start the immunization series remain susceptible to infection. Poor field efficacy is of particular concern in regions with high hepatitis B prevalence and constitutes a major public health issue.

**Hepatitis B Therapy**

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

Our product candidate for hepatitis B therapy, 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 350 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.

## 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 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 conducted a Phase I trial to evaluate the safety and tolerability of inhaled 1018 ISS in 54 healthy subjects. In the first part of the trial, ISS was found to be well tolerated at escalating doses. In the second part of the trial, measurable increases in the expression of cytokines induced by 1018 ISS were observed in treated patients relative to placebo, confirming our understanding of its mechanism of action. We have completed a Phase IIa trial in Canada to evaluate the preliminary safety and tolerability of 1018 ISS in mild asthmatics and assess the efficacy of the treatment following allergen challenge. In this trial, 39 patients were given four weekly doses of either 1018 ISS or placebo. The primary endpoint of this trial was a comparison between 1018 ISS and placebo of the allergen-induced clinical symptoms following the final dose. The safety results of the trial showed no differences in treatment-emergent or drug-related adverse events or in serious adverse events. ISS produced statistically significant elevations, in both peripheral blood and induced sputum, of genes induced by alpha interferon, the main agent in the biological cascade triggered by ISS. No induction of these genes was observed in the placebo-treated patients. After allergen challenges at weeks two and four, no significant changes in pulmonary function were observed between placebo and treated groups. We anticipate initiating a Phase II study in late 2005.

#### *Commercial Opportunity*

Asthma is a chronic disorder caused primarily by allergic inflammation of the airways, leading to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly in the night or early morning. If not properly managed, asthma can be life threatening. Asthma affects more than 300 million individuals worldwide. In the U.S. alone, asthma is estimated to afflict 20 million people. The incidence of asthma is increasing and often occurs in response to triggering allergens. It is estimated that at least 75% of patients with asthma also complain of allergic symptoms and 20-30% of those with allergic rhinitis also have asthma. Sales of asthma drugs worldwide approximated $9.0 billion in 2002.

#### *Current Asthma Therapies and their Limitations*

Current asthma therapies are aimed at suppressing or manipulating the immune and inflammatory components of asthma. The most common therapy is the use of inhaled corticosteroids that reduce swelling and inflammation. The requirement for daily administration of inhaled corticosteroids to treat chronic asthma often leads to poor compliance, especially in younger patients. Other approaches include inhaled beta-agonists for bronchodilation and leukotriene inhibitors to control inflammation (these are delivered orally but demonstrate only modest efficacy). The most recent entrant to the asthma treatment market is an anti-IgE antibody, co-promoted by Tanox, Genentech and Novartis, that is administered every two to four weeks by injection for moderate to severe allergic asthma and is priced at over $10,000 per year.

**Additional Programs**

In addition to our primary product portfolio, we are pursuing earlier stage programs in Next-Generation Vaccines, Cancer, Antiviral Applications and Chronic Inflammation, 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 the third quarter of 2003, the National Institute of Allergy and Infectious Diseases, or NIAID, awarded us a $3.7 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 37 years ago, 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. While nucleoprotein alone is not capable of inducing a protective immune response, 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. In the third quarter of 2003 we were awarded a $3.0 million grant over three and a half years to fund research and development of an advanced pandemic 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

Tumor necrosis factor alpha, or TNF-alpha, is a cytokine that plays a major role in the body's response to infectious diseases. Following bacterial or viral infection, TNF-alpha is normally released as part of a Th1-dominated immune response to fight the invading pathogen. In a number of diseases, such as rheumatoid arthritis, Crohn's disease and psoriasis, however, inappropriately high levels of this cytokine are produced, leading to the debilitating symptoms of these conditions. A number of published studies have shown that inhibition of TNF-alpha is effective in the treatment of these diseases.

We are developing drugs based on a novel class of chemical compounds called thiazolopyrimidines, or TZPs, for the treatment of rheumatoid arthritis, a form of inflammatory bowel disease called Crohn's disease and other TNF-alpha mediated 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.

We are conducting preclinical studies to determine the mechanism of action of TZPs as well as evaluate their activity ex-vivo. Based on the outcome of these studies, we will determine whether to initiate clinical trials using TZPs in rheumatoid arthritis, Crohn's disease or potentially in other inflammatory diseases.

In June 2003, we entered into a development collaboration agreement with BioSeek, Inc. to conduct studies to determine the mechanism of action for TZPs. Under the terms of the agreement, a milestone payment is payable to BioSeek upon the achievement of a milestone and royalties are payable if we partner or commercialize our TZP program. The agreement may be terminated by either party. As of December 31, 2004, BioSeek achieved the contractual milestone, and as a result, we recorded an accrual for $0.3 million.

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 erythematosis (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 three main technology areas: ISS, TZP and vaccines using DNA. 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 seventeen issued U.S. and foreign patents, thirty-two pending U.S. patent applications, and eighty-six pending foreign applications that seek worldwide coverage of compositions and methods using ISS technology. Some of these patents and applications have been exclusively licensed worldwide from the Regents of the University of California. Among others, we hold issued

U.S. patents covering 1018 ISS as a composition of matter; the use of ISS alone to treat asthma; and ISS linked to allergens and viral or tumor antigens.

- *TNF-alpha inhibitors:* We have sixteen issued U.S. and foreign patents and six 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 fourteen issued U.S. and foreign patents and nine 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.

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 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 U.S., including AIC. In December 2003 the United States 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 names 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. If successful, the interference action would establish our founders as the inventors of the inventions in dispute. 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 non-final decision. 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.

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.

AIC 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, AIC was produced for us by a single contract manufacturer. Our existing supplies of AIC are sufficient for us to conduct our currently planned Phase III clinical trial in a pediatric indication. We plan to qualify and enter into manufacturing agreements with one or more new commercial manufacturers to produce additional supplies of AIC as required for completion of clinical trials and commercialization.

Our hepatitis B vaccine consists of ISS combined with clinical grade hepatitis B surface antigen using standard fill and finish 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, under which Berna will provide a supply of antigen necessary to permit us to commence our planned Phase III trials and to commercialize our hepatitis B vaccine product candidate.

**Marketing**

We have no sales, marketing or distribution capability. We intend to seek global or regional partners to help us market certain product candidates. Although we have not yet determined our commercialization strategy for our other product candidates, we are inclined to license commercial rights to larger pharmaceutical or biotechnology companies with appropriate marketing and distribution capabilities, except in instances where it may prove feasible to build a small direct sales organization targeting a narrow specialty or therapeutic area.

**Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many of our competitors, including biotechnology and pharmaceutical companies, academic institutions and other research organizations, are actively engaged in the discovery, research and development of products that could compete directly or indirectly with our products under development.

If AIC 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 and Allergy Therapeutics are developing enhanced allergy immunotherapeutic products formulated for both injection and sublingual delivery. We believe that our AIC 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 AIC 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, 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, will 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 injectable 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.

**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;
- 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 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.

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, 2005, we had 71 full-time employees, including 14 Ph.D.s, 3 M.D.s and 4 others with advanced degrees. Of the 71 employees, 49 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.

**Executive Officers and Key Employees**

Our executive officers and key employees and their respective ages as of February 28, 2005 are as follows:

| Name | Age | Position |
|---|---|---|
| Dino Dina, M.D. | 58 | President, Chief Executive Officer, and Director |
| Robert L. Coffman, Ph.D. | 58 | Vice President and Chief Scientific Officer |
| Jane M. Green, Ph.D. | 53 | Vice President, Corporate Communications |
| Timothy G. Henn | 47 | Vice President, Finance & Administration and Chief Accounting Officer |
| D. Kevin Kwok, Pharm.D. | 43 | Vice President and Chief Business Officer |
| Daniel Levitt, M.D., Ph.D. | 57 | Vice President and Chief Medical Officer |
| Deborah A. Smeltzer | 51 | Vice President, Operations and Chief Financial Officer |
| Stephen F. Tuck, Ph.D. | 43 | Vice President, Biopharmaceutical Development |
| Gary A. Van Nest, Ph.D. | 55 | Vice President, Preclinical Research |

*Dino Dina, M.D.* has been our President and a member of our Board of Directors since May 1997 and our Chief Executive Officer since May 1998. From 1982 until he joined us in 1997, Dr. Dina was an employee of Chiron Corporation, a biopharmaceutical company. At Chiron, Dr. Dina held a series of positions with increasing responsibility. He ultimately served as president of Chiron Vaccines (formerly Biocine Company), which he directed from its inception in 1987. Under Dr. Dina's direction, Chiron Vaccines received the first-ever approval of an adjuvanted influenza vaccine in Italy, successfully completed development of the first genetically engineered pertussis vaccine, and conducted clinical trials for vaccines to prevent HIV, herpes simplex type II, cytomegalovirus, and hepatitis B infections. The virology group he directed was responsible for several key scientific findings, including the discovery, cloning, and sequencing of the hepatitis C virus, and the cloning and sequencing of the viral genomes for HIV and hepatitis A viruses. Prior to joining Chiron, Dr. Dina was employed at Albert Einstein College of Medicine in Bronx, New York, as an assistant professor of genetics from 1977 to 1982. He received his M.D. from the University of Genoa Medical School in Italy.

*Robert L. Coffman, Ph.D.* has been our Vice President and Chief Scientific Officer since December 2000. Dr. Coffman joined Dynavax from the DNAX Research Institute where he had been since 1981, most recently as Distinguished Research Fellow. Prior to that, he was a postdoctoral fellow at Stanford University Medical School. Dr. Coffman has made fundamental discoveries about the regulation of immune responses in allergic and infectious diseases. He shared the William S. Coley Award for Research in Immunology for discovery of the Th1 and Th2 subsets of T lymphocytes, the cells that control most immune responses. Dr. Coffman received his Ph.D. from the University of California, San Diego and his AB from Indiana University.

*Jane M. Green, Ph.D.* joined Dynavax in September 2004. Dr. Green is responsible for the Company's external and internal communications programs, including investor relations, public relations, media relations, and communications strategy. Prior to Dynavax, Dr. Green was Vice President, Corporate Communications at Exelixis, Inc. where she developed and managed the Company's communications strategy to support its transition from a technology to product-focused enterprise. Prior to Exelixis, Dr. Green was Senior Director at Caliper Technologies where she coordinated the company's initial public offering and established the corporate communications and investor relations function. Dr. Green brings over 20 years of experience in corporate communications, investor relations, and marketing communications. Dr. Green holds a BA in literature from the University of Pennsylvania and a Ph.D. in English literature from the State University of New York at Buffalo.

*Timothy G. Henn* has been our Chief Accounting Officer since January 2005 and our Vice President, Finance & Administration since August 2004. Prior to Dynavax, Mr. Henn was at Incyte Corporation from 1997 to 2004, where he was most recently Senior Vice President, Finance and Corporate Controller, having responsibility for company wide accounting, financial planning, and purchasing. He brings over 20 years of experience in accounting and finance, and has been instrumental in numerous strategic, financial and operational activities. Mr. Henn received his MBA from Golden Gate University and his BS in accounting from the University of Illinois.

*D. Kevin Kwok, Pharm.D.* has been our Vice President and Chief Business Officer since March 2004. He was most recently Vice President for the Transaction Advisory Group at Clearview Projects, where he was responsible for the start-up and client management of the San Francisco practice. He brings more than 18 years of diverse industry experience with both pharmaceutical and biotechnology companies in various commercial areas. Prior to Clearview Projects, Dr. Kwok directed global strategic marketing, business development, and corporate development at SUGEN from 1997 to 2000. After its merger with Pharmacia, he led strategic marketing and brand management for the Company's joint angiogenesis portfolio in oncology. Previously, he also has held various management positions in U.S. and international marketing, sales, new business ventures, and other areas at Bristol-Myers Squibb and the Upjohn Company. Dr. Kwok earned his Doctor of Pharmacy degree from the University of Michigan.

*Daniel Levitt, M.D., Ph.D.* has been our Vice President and Chief Medical Officer since August 2003 and is responsible for our clinical, regulatory, and medical affairs. From 2002 until he joined us in 2003, Dr. Levitt was chief operating officer and head, research and development at Affymax. From 1996 to 2002, Dr. Levitt was senior vice president, drug development, and then president, research and development, at Protein Design Labs, Inc. Prior to Protein Design Labs, he had a successful and progressive career in scientific management, clinical, and regulatory affairs at Geron, from 1995 to 1996, Sandoz, from 1990 to 1995, and Hoffman-LaRoche, from 1986 to 1990. His academic appointments included Senior Scientist and Associate Director at the Guthrie Research Institute in Sayre, Pennsylvania from 1983 to 1986 and Assistant Professor of Pediatrics and Immunology at the University of Chicago Hospitals and Clinics from 1980 to 1983. He earned his M.D. and Ph.D. in biology from the University of Chicago, completed his residency at Yale-New Haven Hospital, was a clinical and research fellow at the University of Alabama Medical Center from 1977 to 1980 and graduated magna cum laude, Phi Beta Kappa from Brandeis University.

*Deborah A. Smeltzer* joined Dynavax in January 2005 as Vice President, Operations and Chief Financial Officer. Previously she was with Applied Biosystems from 1999 through 2004, where she served most recently as Vice President and General Manager of the company's genetic analysis business. She previously served as Vice President and General Manager of the company's knowledge business and Vice President, Finance for the organization with responsibility for business development. Prior to Applied Biosystems, Ms. Smeltzer served as Chief Financial Officer and Vice President for Genset SA, a Paris-based global genomics company, from 1996 to 1999. Ms. Smeltzer brings to Dynavax more than 20 years of operating, business, and financial management experience, including venture capital, investment banking, academic research, and quality assurance. She holds a BS in biological sciences and an MS in medical microbiology from the University of California, Irvine, and an MBA from Stanford University Graduate School of Business.

*Stephen F. Tuck, Ph.D.* has been our Vice President, Biopharmaceutical Development since November 2000 and previously served as our Senior Director of Biopharmaceutical Development since joining us in November 1997. From 1992 until he joined us in 1997, Dr. Tuck was employed by Chiron Corporation, where he had served in various capacities in the Technical Affairs and Process Development departments. At Chiron, Dr. Tuck was involved in the development of Fluad®, a novel adjuvanted influenza vaccine, various subunit vaccines, adjuvants and protein therapeutics. Prior to joining Chiron, Dr. Tuck was a post-doctoral fellow at Johns Hopkins University School of Medicine and the University of California, San Francisco. He has over 15 years of experience in pharmaceutical chemistry. Dr. Tuck received his Ph.D. and B.Sc. from Imperial College, University of London.

*Gary A. Van Nest, Ph.D.* has been our Vice President, Preclinical Research since November 2000 and previously served as our Senior Director of Preclinical Research since joining us in November 1997. From

1982 until he joined us in 1997, Dr. Van Nest was employed by Chiron Corporation, where he served in several positions of increasing responsibility culminating in a position as Acting Head of Vaccine Research. At Chiron, Dr. Van Nest directed the development of novel adjuvants and delivery vehicles for subunit vaccines for herpes, HIV, influenza, hepatitis B virus, hepatitis C virus and cytomegalovirus. Dr. Van Nest has authored over 40 publications. He received his Ph.D. in biochemistry from the University of Arizona and his BA from the University of California, Riverside.

## ITEM 2. PROPERTIES

The Company leases approximately 67,000 square feet of laboratory and office space in Berkeley, California, 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.

## 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.

| | Common Stock Price | |
|---|---|---|
| 2004 | High | Low |
| 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, 2005, there were approximately 112 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.

### Equity Compensation Plan Information

The information under the caption Equity Compensation Plan Information appearing in the Proxy Statement is incorporated herein by reference.

### Use of Proceeds from Sales of Registered Securities

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 (which was exercised in full) 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 approximately $46.5 million. These proceeds are 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. During 2004, the net proceeds were used for research and development activities and general corporate purposes. We will retain broad discretion over the use of the net proceeds received from our offering. 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.

## 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, 2004, 2003 and 2002 and the Consolidated Balance Sheets Data as of December 31, 2004 and 2003 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, 2001 and 2000 and the Consolidated Balance Sheets Data as of December 31, 2002, 2001 and 2000 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, | | | | |
|---|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (In thousands, except per share data) | | | | |
| **Consolidated Statements of Operations Data:** | | | | | |
| Collaboration and grant revenues | $ 14,812 | $ 826 | $ 1,427 | $ 2,359 | $ 2,054 |
| Operating expenses: | | | | | |
| Research and development | 23,129 | 13,786 | 15,965 | 17,363 | 8,267 |
| General and administrative | 8,543 | 4,804 | 4,121 | 4,527 | 3,451 |
| Total operating expenses | 31,672 | 18,590 | 20,086 | 21,890 | 11,718 |
| Loss from operations | (16,860) | (17,764) | (18,659) | (19,531) | (9,664) |
| Interest income, net | 889 | 412 | 621 | 1,119 | 1,149 |
| Deemed dividend | — | (633) | — | — | — |
| Net loss attributable to common stockholders | $ (15,971) | $ (17,985) | $ (18,038) | $ (18,412) | $ (26,724) |
| Basic and diluted net loss per share attributable to common stockholders | $ (0.75) | $ (10.04) | $ (10.65) | $ (12.29) | $ (22.59) |
| Shares used in computing basic and diluted net loss per share attributable to common stockholders | 21,187 | 1,791 | 1,694 | 1,498 | 1,183 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (In thousands) | | | | |
| **Consolidated Balance Sheets Data:** | | | | | |
| Cash, cash equivalents and marketable securities | $ 65,844 | $ 29,097 | $ 29,410 | $ 11,757 | $ 26,792 |
| Working capital | 64,017 | 26,340 | 25,913 | 9,498 | 26,578 |
| Total assets | 73,646 | 31,585 | 31,478 | 15,117 | 29,590 |
| Equipment financing, net of current portion | — | — | — | — | 15 |
| Minority interest in Dynavax Asia | — | 14,733 | — | — | — |
| Mandatorily redeemable convertible preferred stock | — | — | — | 45,479 | 45,486 |
| Convertible preferred stock | — | 83,635 | 83,635 | 5,799 | 5,799 |
| Accumulated deficit | (95,336) | (79,365) | (62,013) | (43,975) | (25,563) |
| Total stockholders' equity (net capital deficiency) | 59,876 | (71,932) | (56,371) | (40,216) | (23,798) |

## 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 enhance the ability of the immune system to fight disease and control chronic inflammation. ISS are being developed in three initial indications: a ragweed allergy immunotherapeutic, a hepatitis B vaccine, and an asthma immunotherapeutic.

We have developed a novel injectable product candidate to treat ragweed allergy that we call AIC. AIC has completed Phase II trials, and is currently completing a two-year Phase II/ III clinical trial. At the end of 2004, we reported that the one-year interim analysis of this Phase II/ III trial showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season. We intend to complete the Phase II/ III clinical trial as planned. We anticipate initiating a supportive Phase III clinical trial in a pediatric indication in the first half of 2005. Pending the outcome of discussions with the US Food and Drug Administration (FDA) in 2005 and the results of the Phase II/III study, we plan to initiate a pivotal Phase III clinical program in early 2006.

We have developed a product candidate for hepatitis B therapy. A Phase II/ III trial in subjects who are less responsive to conventional vaccine is currently underway in Singapore. Results from an interim analysis of the Phase II/ III trial showed that our vaccine demonstrated statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B™ vaccine. We anticipate initiating Phase III trials in Canada, Europe and Asia in 2005, pending the outcome of the current trial. Our intention is to initially commercialize our hepatitis B vaccine outside of the United States.

We have an inhaled therapeutic product candidate for treatment of asthma, which has completed a Phase IIa trial in Canada. Results from a Phase IIa asthma challenge study confirmed the safety of inhaled immunostimulatory sequences in asthmatic patients, and showed substantial and statistically significant pharmacological activity, based upon the induction of genes associated with a reprogrammed immune response. We anticipate initiating a Phase II study in asthma in late 2005.

For the year ended December 31, 2004, our net loss was $16.0 million, compared to $17.4 million in 2003 and $18.0 million in 2002. As of December 31, 2004, we had an accumulated deficit of $95.3 million. We expect to incur substantial and increasing losses as we continue the development of the 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.

We do not have any products that generate revenue. Total revenues for the year ended December 31, 2004 were $14.8 million, compared to $0.8 million for 2003 and $1.4 million for 2002. For the fiscal year ended December 31, 2004, 93% of our revenues were derived from a collaboration agreement and the remaining revenues were earned from government grants for biodefense programs. For the fiscal year ended December 31, 2003, our revenue was derived solely from government grants. Through the fiscal year ended December 31, 2002, we generated revenue primarily through research and development collaboration agreements.

During 2004, we completed our initial public offering of common stock, continued to advance our clinical programs, and expanded our senior management team. For the year ended December 31, 2005, excluding the potential impact of any equity offerings, business collaborations or other transactions that may be entered into, we anticipate that our operating expenses will increase in connection with our growing clinical development programs and overall organizational growth. Currently, total revenues consist primarily of revenue recognized from our development and commercialization collaboration with UCB Farchim, SA (UCB). In March 2005, we agreed to end the collaboration agreement with UCB.

**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.* In accordance with the criteria outlined in Staff Accounting Bulletin (SAB) No. 104, “Revenue Recognition” and Emerging Issues Task Force (EITF) Issue 00-21, “Revenue Arrangements with Multiple Deliverables,” 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 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 Expense and Related Accruals.* Research and development expenditures are charged to operations as incurred. Research and development expense consists of the direct and indirect internal costs of specific functional areas, as well as fees paid to contract research organizations, research institutions, contract manufacturing organizations, and other service providers which conduct certain research and development activities on behalf of the Company.

Preclinical and clinical studies are a significant component of research and development expense. We accrue costs related to clinical trials on a straight-line basis over the term of the service period based on our initial estimate that the work performed under the contracts occurs ratably over the periods to the expected milestone, event or total contract completion date. The estimates may or may not match the actual services performed by research institutions and contract research organizations that conduct and manage clinical trials on our behalf, as determined by patient enrollment levels and other measures of activities specified in the contract. As a result, we adjust our estimates at the end of each reporting period, if required, based on our ongoing review of the level of effort actually incurred by the organizations.

The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under these contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. 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, regardless of payment status.

*Stock-Based Compensation.* Statement of Financial Accounting Standards (FAS) 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 FAS No. 123, as amended by FAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." As permitted under FAS No. 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 FAS No. 123, as amended by FAS No. 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."

We record deferred stock compensation as a component of stockholders' equity in connection with the grant of stock options to employees and non-employees. For options granted to employees, deferred stock compensation is calculated 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. For stock options granted to non-employees, deferred stock compensation is calculated based on the fair value of the options using the Black-Scholes valuation model on the date of grant. Periodically, we re-measure the estimated fair value of unvested options granted to non-employees and adjust deferred stock compensation accordingly. Deferred stock compensation is amortized as a charge to operations using the straight-line method over the vesting option period, ranging up to 4 years. The amount of stock-based compensation expense to be recorded in future periods may decrease if unvested options, for which deferred stock compensation has been recorded, are subsequently canceled.

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. The Black-Scholes option valuation 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. The expected stock price volatility was estimated 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, based on the vesting cycle. 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 FAS No. 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, 2004, 2003 and 2002 (in thousands, except percentages):

| | Years Ended December 31, | | | Increase (Decrease) from 2004 to 2003 | | Increase (Decrease) from 2003 to 2002 | |
|---|---|---|---|---|---|---|---|
| Results of Operations: | 2004 | 2003 | 2002 | $ | % | $ | % |
| Revenues: | | | | | | | |
| Collaboration revenue | $ 13,782 | $ — | $ 1,427 | $ 13,782 | N/A | $ (1,427) | (100)% |
| Grant revenue | 1,030 | 826 | — | 204 | 25% | 826 | —% |
| Total revenues | $ 14,812 | $ 826 | $ 1,427 | $ 13,986 | 1,693% | $ (601) | (42)% |
| Operating expenses: | | | | | | | |
| Research and development | $ 23,129 | $ 13,786 | $ 15,965 | $ 9,343 | 68% | $ (2,179) | (14)% |
| General and administrative | 8,543 | 4,804 | 4,121 | 3,739 | 78% | 683 | 17% |
| Total operating expenses | $ 31,672 | $ 18,590 | $ 20,086 | $ 13,082 | 70% | $ (1,496) | (7)% |
| Interest income, net | $ 889 | $ 412 | $ 621 | $ 477 | 116% | $ (209) | (34)% |
| Deemed dividend upon issuance of ordinary share of Dynavax Asia | $ — | $ 633 | $ — | $ (633) | (100)% | $ 633 | N/A |

***Revenues***

Total revenues for the year ended December 31, 2004 were $14.8 million, consisting of $13.8 million from our collaborative agreement with UCB in ragweed and grass allergies, which was initiated in the first quarter of 2004, and $1.0 million from government grants. In March 2005, we agreed to end the development and commercialization collaboration agreement with UCB.

Total revenues for the years ended December 31, 2003 and 2002 were $0.8 million and $1.4 million, respectively. Revenues for the year ended December 31, 2003 resulted entirely from NIH grants. The National Institutes of Health (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. Revenues for the year ended December 31, 2002 resulted from two research and development collaboration agreements and another agreement providing a customer with an option to negotiate rights to license technology we developed. The first of these two collaborations, focused on infectious diseases, was terminated by mutual consent in September 2002 and provided revenues of $1.0 million for the year ended December 31, 2002. The second of these two collaborations, focused on the treatment and prevention of hepatitis and HIV, was terminated in November 2002 and provided revenues of $0.2 million for

the year ended December 31, 2002. The agreement with a customer lapsed in April 2002 when the customer did not exercise its option and generated revenues of $0.2 million for the year ended December 31, 2002.

***Research and Development***

Research and development expense consists of the costs of our preclinical experiments and clinical trials, activities related to regulatory filings, manufacturing our product candidates for our preclinical experiments and clinical trials, compensation and related benefits, allocated facility costs, supplies and depreciation of laboratory equipment. We expense our research and development costs as they are incurred.

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 over the prior year was primarily due to $6.5 million in increased clinical trial and clinical manufacturing costs associated with our ragweed allergy and hepatitis B vaccine programs, as well as $1.1 million in increased preclinical work associated with government grants for biodefense programs. Facilities costs rose by $0.8 million as a result of increased rent and operating costs for our facility, and compensation and related benefits increased by $0.9 million due to growth in headcount from 36 employees as of December 31, 2003 to 50 employees as of December 31, 2004. Non-cash stock-based compensation expense included in research and development expenses was $1.3 million for the year ended December 31, 2004.

Research and development expenses of $13.8 million for the year ended December 31, 2003 decreased by 14% from the $16.0 million reported for the year ended December 31, 2002. This decrease was primarily the result of fewer and less extensive clinical trials in our hepatitis B vaccine and asthma programs being conducted during the year ended December 31, 2003. Non-cash stock-based compensation expense included in research and development expense was approximately $1.3 million and $1.0 million for the year ended December 31, 2003, and 2002, respectively.

During 2005, we anticipate that our research and development expense will increase in connection with our growing clinical development programs, including our plans to initiate a supportive Phase III AIC trial in a pediatric indication anticipated to begin in 2005, and Phase III clinical trials for our hepatitis B vaccine which we expect to initiate in 2005.

***General and Administrative***

General and administrative expense consists primarily of compensation and related benefits, professional expenses, such as legal, accounting, consulting and public relations, insurance and allocated facility 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, reflecting higher costs of operating as a public company. The increase over the prior year includes $1.7 million in higher expenditures for legal, accounting, consulting and insurance costs, as well as $0.7 million in higher compensation, benefits and recruitment costs, primarily associated with the expansion of our management team and overall organizational growth. General and administrative headcount increased from 12 employees as of December 31, 2003 to 21 employees as of December 31, 2004. Non-cash stock-based compensation expense included in general and administrative expense was approximately $1.5 million for the year ended December 31, 2004.

General and administrative expenses of $4.8 million for the year ended December 31, 2003 increased by 17% over the $4.1 million reported for the year ended December 31, 2002. This increase reflects higher compensation and benefits during the year ended December 31, 2003 associated with the addition of our management team and expenditures for consulting services. Non-cash stock-based compensation expense included in general and administrative expense was approximately $0.5 million and $0.9 million for the years ended December 31, 2003, and 2002, respectively.

During 2005, we expect general and administrative expenses to increase primarily resulting from the full year impact of organizational growth that occurred in 2004.

***Interest Income, Net***

Interest income, net of interest expense and amortization on marketable securities, was $0.9 million for the year ended December 31, 2004. The increase was primarily due to the interest income related to the proceeds from our initial public offering and a higher average marketable securities balances during 2004. Interest income, net was $0.4 million for the year ended December 31, 2003 compared to $0.6 million reported for the year ended December 31, 2002. The decrease was primarily due to lower average cash balances during the year ended December 31, 2003.

***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 December 16, 2004, the FASB issued FAS No. 123R (revised 2004), “Share-Based Payment,” that requires all share-based payments to employees, including grants of employee stock options, to be recognized based on their fair values. Pro forma disclosure is no longer an alternative. FAS No. 123R supersedes APB No. 25, “Accounting for Stock Issued to Employees,” and amends FAS No. 95, “Statement of Cash Flows.” Under FAS No. 123R, share-based payments 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. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Public companies are allowed to select from three alternative transition methods–each having different reporting implications. FAS No. 123R is effective for interim and annual periods beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date. Although we have elected to follow the intrinsic value method prescribed by APB No. 25 through the year ended December 31, 2004, we will adopt FAS No. 123R in 2005. The adoption of FAS No. 123R’s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because we are in the process of reevaluating our methodology used to determine fair value, including consideration of an option-pricing model and related assumptions. In addition, the impact of adoption will depend on levels of share-based payments granted in the future. However, we believe that had we adopted FAS No. 123R in prior periods using the Black-Scholes model, the impact of that standard could have approximated the impact as described in the disclosure of pro forma net loss and net loss per share in Note 1 to the 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 $144.8 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 of approximately $46.5 million from the sale of 6,900,000 shares of common stock. As of December 31, 2004, we had approximately $65.8 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 $7.3 million during the year ended December 31, 2004 declined from the $14.4 million used during the year ended December 31, 2003. The decrease from the prior year of $7.1 million was due primarily to an $8.0 million upfront payment made to us by UCB and a narrower net loss from operations, partially offset by an increase in working capital. Cash used in operating activities during the

year ended December 31, 2003 increased by $0.4 million over 2002, due primarily to an increase in working capital, partially offset by a decrease in net loss.

Cash used in investing activities of $46.0 million during the year ended December 31, 2004 consisted primarily of net purchases of investments of $44.1 million in addition to purchases of property and equipment of $1.9 million. Cash provided by investing activities of $17.8 million during the year ended December 31, 2003, consisted primarily of maturities and net sales of investments of $18.0 million. Cash used in investing activities of $17.6 million during the year ended December 31, 2002 primarily included net purchases of investments of $17.1 million.

Our financing activities provided cash of $46.4 million during the year ended December 31, 2004, primarily from the issuance of 6,900,000 shares of common stock in our initial public offering in February 2004. Cash provided by financing activities of $14.9 million during the year ended December 31, 2003 consisted primarily of $14.7 million in net proceeds from the 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. Cash provided by financing activities of $32.4 million during the year ended December 31, 2002 included $32.4 million in net proceeds from the issuance of preferred stock.

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, 2005, primarily due to cash used for operations.

The following summarizes our significant contractual obligations as of December 31, 2004, and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations:** | **Total** | **Less than 1 Year** | **1-3 Years** | **4-5 Years** | **After 5 Years** |
| Future minimum payments under our operating lease | $ 8,123 | $ 1,649 | $ 3,447 | $ 3,027 | $ — |
| Total | $ 8,123 | $ 1,649 | $ 3,447 | $ 3,027 | $ — |

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. We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to us of $104,656 in 2004 and $339,990 annually thereafter 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.

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, 2004 and is collateralized by a certificate of deposit which has been included in restricted cash in the Consolidated Balance Sheets as of 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, 2004, under the terms of an agreement with a contract research organization, we are obligated to make future payments as services are provided up to $3.0 million in 2005.

In February 2004, we entered into an agreement with UCB in which we licensed the technology, know-how, and preclinical and clinical data related to our AIC and grass allergy programs to UCB on an exclusive, worldwide basis. According to terms of the agreement, we received an upfront payment of $8.0 million. In March 2005, we agreed to end our development and commercialization collaboration with UCB. Under the terms of the agreement, UCB will return all rights to the allergy program to Dynavax and the current ongoing Phase II/ III clinical trial of our AIC immunotherapy for ragweed allergy will be completed as planned. Dynavax will assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to AIC and for preclinical development programs in grass and in peanut allergy. The agreement also provides for the partial reimbursement of certain patent interference fees and expenses, subject to a maximum amount. In 2004, the reimbursement amount was negligible.

Under the terms of the exclusive license agreements with the Regents of the University of California, we are obligated to pay milestones and royalties on net sales of products originating from the licensed technologies. As partial consideration for the technology licenses, during 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 upfront payment from UCB. No other milestones were achieved as of December 31, 2004.

Under the development collaboration agreement with BioSeek, Inc., we will make various payments for the achievement of a milestone and 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. As of December 31, 2004, we recorded an accrual of $0.3 million associated with the achievement of the contractual milestone.

Under the terms of an agreement with Berna Biotech, 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, 2004.

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.

**Risk Factors**

*Various discussions in this Annual Report on Form 10-K contain 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. Currently, our revenue results from a collaboration agreement and government grants for biodefense programs. The collaboration agreement is subject to termination under specified circumstances. The grants are subject to annual review based on the achievement of milestones and other factors and will terminate in 2006 at the latest. Our accumulated deficit was $95.3 million as of December 31, 2004, 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 2004, we began Phase II/ III trials for AIC, an immunotherapy for ragweed allergy, and Phase II/ III trials for our hepatitis B vaccine. Our 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 planned Phase III trials for AIC and our hepatitis B vaccine;
- obtaining regulatory approvals for our product candidates in the U.S. and international markets;
- 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
- commercial acceptance of our products, in particular AIC and our hepatitis B vaccine.

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. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. 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. We may also need to secure more funding than currently anticipated because we may change our product development plans or clinical programs.

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 proven safe and effective in clinical trials or approved for sale in the U.S. or any foreign market. Any product candidate we develop is subject to extensive regulation by Federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for AIC, our ragweed allergy product candidate, and our hepatitis B vaccine product candidate. We intend to commercialize our hepatitis B vaccine initially outside the U.S., which will require us to seek approval from foreign regulatory agencies. Approval processes in the U.S. 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.

Currently, only three of our product candidates have advanced to Phase II clinical trials: AIC, our hepatitis B vaccine and our inhaled therapeutic for treatment of asthma. We have only limited clinical data for these product candidates, some of which may not be supportive of ultimate regulatory approval. We will need to demonstrate in Phase III clinical trials that each product candidate is safe and effective before we can obtain necessary approvals from the FDA and foreign regulatory agencies. We initiated a two-year, multi-site Phase II/ III trial in the first quarter of 2004 in the U.S. for AIC. Pending the outcome of discussions with the FDA in 2005 and the results of the Phase II/III study, we plan to initiate a pivotal Phase III clinical program in early 2006. We also anticipate initiating Phase III trials for our hepatitis B vaccine in Canada, Europe and Asia in 2005. 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 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 and concerns regarding health risks to test subjects. In addition, our ability to conduct clinical trials for some of our product candidates, notably AIC and our asthma product candidate, is limited due to the seasonal nature of ragweed allergy and allergic asthma. Even a small delay in a trial for any of these product candidates could require us to delay commencement of the trial until the next appropriate season, which could result in a delay of an entire year. Consequently, we may experience additional delays in obtaining regulatory approval for these product candidates.

Suspension, termination or unanticipated delays of our clinical trials for AIC, hepatitis B, or asthma 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; and
- limit our ability to obtain additional financing on acceptable terms, if at all.

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

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 have 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 for our hepatitis B vaccine and hepatitis B therapeutic product candidates. Our collaboration agreement with UCB for AIC and grass allergy immunotherapy ended in March 2005. 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 funding.

**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 contract relationships with third parties to obtain the component materials that are necessary for our clinical product candidates and to manufacture our product candidates for clinical trials. Termination or interruption of these relationships may occur due to circumstances that are outside our control, resulting in higher costs or delays in our product development efforts.

In particular, we have relied on a single supplier to produce our ISS for clinical trials. ISS is a critical component of both of our AIC and hepatitis B vaccine product candidates. 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 potential delays in 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 AIC or enough AIC to supply ongoing clinical and, potentially, commercial needs. We believe that our existing supplies of AIC are sufficient for us to conduct our currently planned Phase III clinical trial in a pediatric indication. We intend to qualify and enter into manufacturing agreements with one or more new commercial-scale contract manufacturers to produce additional supplies of AIC as required for completion of clinical trials and commercialization. If we are unable to complete such agreements, we would have to establish an internal commercial scale manufacturing capability for AIC, incurring increased capital and operating costs, delays in the commercial development of AIC 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 Phase II/ III clinical trials for AIC and Phase II/ III trials for our hepatitis B vaccine. 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 AIC or our hepatitis B vaccine.**

We are unable to independently conduct our planned clinical trials for AIC or our hepatitis B vaccine, 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 AIC or our hepatitis B vaccine 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.**

We do not anticipate that any of our product candidates will be commercially available until 2007 at the earliest, if at all. Furthermore, even 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 AIC, 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 our product. We believe that market acceptance of AIC 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.

We expect that Asia will be the primary target market for our hepatitis B vaccine, if approved. While we may seek partners for purposes of commercializing this product candidate in Asian and other non-U.S. markets in addition to or as a replacement for our current collaborative partner, which has an exclusive option to commercialize our hepatitis B vaccine 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 our hepatitis B vaccine 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 due to health care reform and heightened scrutiny from 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.

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

Our hepatitis B vaccine, if approved, will compete with existing three-shot vaccines produced by GlaxoSmithKline Plc and Merck & Co., Inc., among others, as well as potentially with a two-shot vaccine in clinical development by GlaxoSmithKline Plc.

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 intend to develop, seek regulatory approval for and market our product candidates outside the U.S., requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our hepatitis B vaccine and therapeutic product candidates.**

We plan to introduce our hepatitis B vaccine in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. 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 our hepatitis B vaccine 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.

**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 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 U.S. and foreign patent applications. Legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved. The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty, given that several of our product candidates may address market opportunities outside the U.S. For example, we expect to market our hepatitis B vaccine, if approved, in foreign countries with high incidences of hepatitis B, particularly in Asia. 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.

**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 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. If we are unsuccessful in defending or prosecuting any such claim we could be required to pay substantial damages and we may be unable to commercialize our product candidates or use these proprietary technologies unless we obtain a license from the third party. 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. 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.

In particular, one of our potential competitors, Coley Pharmaceutical Group, or 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 U.S., including AIC. In December 2003 the United States 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 names 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. If successful, the interference action would establish our founders as the inventors of the inventions in dispute. 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 non-final decision. 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 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.

**We expect that our stock price will be volatile, 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 may be 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 AIC and our hepatitis B vaccine;
- progress of regulatory approval of our product candidates, in particular AIC and our hepatitis B vaccine, 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. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, divert management's attention and resources and disrupt our business operations.

**If the ownership of our common stock continues to be highly concentrated, it may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.**

Our executive officers, directors and their affiliates beneficially owned or controlled approximately 41% of our outstanding common stock as of February 28, 2005. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

**Being a public company increases our administrative costs.**

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as new rules subsequently implemented by the Securities and Exchange Commission and new listing requirements subsequently adopted by Nasdaq in response to Sarbanes-Oxley, have required changes in corporate governance practices of public companies. These new rules, regulations, and listing requirements have increased our legal and

financial compliance costs, and made some activities more time consuming and costly. For example, as a result of becoming a public company, we have created several board committees, adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and a financial printer, adopted an insider trading policy, and have all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. These new rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance. These new rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee, and qualified executive officers.

**We are currently reviewing and testing our material internal control systems, processes and procedures in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.**

Sarbanes-Oxley Section 404 requires us to review and test our material internal control systems, processes and procedures to ensure compliance. There can be no assurance that our review and testing of material internal control systems, processes and procedures will not result in the identification of significant control deficiencies or result in an adverse opinion from our independent auditors.

## 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 do not have transactional foreign currency risk because nearly all of our business is transacted in U.S. dollars. As a result, we have little to no exposure to foreign exchange rate fluctuations.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**Report of Ernst & Young LLP, Independent Registered Public Accounting Firm**

To The Board of Directors and Stockholders
Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2004 and 2003, 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, 2004. 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Palo Alto, California
February 4, 2005 except for the second paragraph of Note 7
as to which the date is March 18, 2005

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

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

| | December 31, 2004 | December 31, 2003 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,590 | $ 23,468 |
| Marketable securities | 49,254 | 5,629 |
| Restricted cash | 408 | — |
| Accounts receivable | 3,131 | 220 |
| Prepaid expenses and other current assets | 1,396 | 1,422 |
| Total current assets | 70,779 | 30,739 |
| Property and equipment, net | 2,465 | 828 |
| Other assets | 402 | 18 |
| Total assets | $ 73,646 | $ 31,585 |
| **Liabilities, minority interest, convertible preferred stock, and stockholders' equity (net capital deficiency)** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,391 | $ 1,410 |
| Accrued liabilities | 4,371 | 2,989 |
| Deferred revenues | 1,000 | — |
| Total current liabilities | 6,762 | 4,399 |
| Deferred revenues, noncurrent | 6,750 | 750 |
| Other long-term liabilities | 258 | — |
| Minority interest in Dynavax Asia | — | 14,733 |
| Convertible preferred stock: $0.001 par value; no shares authorized at December 31, 2004 and 61,767 shares authorized at December 31, 2003; no shares outstanding at December 31, 2004 and 39,514 shares issued and outstanding at December 31, 2003 | — | 83,635 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity (net capital deficiency): | | |
| Preferred stock: $0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2004 and 2003 | — | — |
| Common stock: $0.001 par value; 100,000 and 28,333 shares authorized at December 31, 2004 and 2003, respectively; 24,627 and 1,884 shares issued and outstanding at December 31, 2004 and 2003, respectively | 25 | 2 |
| Additional paid-in capital | 159,074 | 12,762 |
| Deferred stock compensation | (3,366) | (4,677) |
| Notes receivable from stockholders | (419) | (654) |
| Accumulated other comprehensive loss | (102) | — |
| Accumulated deficit | (95,336) | (79,365) |
| Total stockholders' equity (net capital deficiency) | 59,876 | (71,932) |
| Total liabilities, minority interest, convertible preferred stock, and stockholders' equity (net capital deficiency) | $ 73,646 | $ 31,585 |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Revenues: | | | |
| Collaboration revenue | $ 13,782 | $ — | $ 1,427 |
| Grant revenue | 1,030 | 826 | — |
| Total revenues | 14,812 | 826 | 1,427 |
| Operating expenses: | | | |
| Research and development | 23,129 | 13,786 | 15,965 |
| General and administrative | 8,543 | 4,804 | 4,121 |
| Total operating expenses | 31,672 | 18,590 | 20,086 |
| Loss from operations | (16,860) | (17,764) | (18,659) |
| Interest income, net | 889 | 412 | 621 |
| Net loss | (15,971) | (17,352) | (18,038) |
| Deemed dividend upon issuance of ordinary shares of Dynavax Asia | — | (633) | — |
| Net loss attributable to common stockholders | $ (15,971) | $ (17,985) | $ (18,038) |
| Basic and diluted net loss per share attributable to common stockholders | $ (0.75) | $ (10.04) | $ (10.65) |
| Shares used to compute basic and diluted net loss per share attributable to common stockholders | 21,187 | 1,791 | 1,694 |

*See accompanying notes.*

**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 Stock Compensation | Notes Receivable From Stockholders | Accumulated Other Comprehensive Income | Accumulated Deficit | Stockholders' Equity (Net Capital Deficiency) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Par Amount | | | | | | |
| Balances at December 31, 2001 | 22,632 | $ 51,278 | 1,902 | $ 2 | $ 9,811 | $ (5,267) | $ (804) | $ 17 | $ (43,975) | $ (40,216) |
| Issuance of Series D convertible preferred stock at $2.06, net of cash issuance costs of $2,420 and non-cash issuance costs of $322 | 16,882 | 32,357 | — | — | — | — | — | — | — | — |
| Issuance of common stock upon exercise of options at $0.30 to $12.00 per share for cash | — | — | 4 | — | 3 | — | — | — | — | 3 |
| Interest accrued on notes receivable from stockholders | — | — | — | — | — | — | (46) | — | — | (46) |
| Repayment of notes receivable from stockholders | — | — | — | — | — | — | 136 | — | — | 136 |
| Common stock repurchased | — | — | (57) | — | (65) | — | — | — | — | (65) |
| Deferred stock compensation | — | — | — | — | (1,326) | 1,326 | — | — | — | — |
| Amortization of deferred stock compensation | — | — | — | — | — | 1,821 | — | — | — | 1,821 |
| Comprehensive loss: | | | | | | | | | | |
| Change in unrealized gain on marketable securities | — | — | — | — | — | — | — | 34 | — | 34 |
| Net loss | — | — | — | — | — | — | — | — | (18,038) | (18,038) |
| Comprehensive loss | | | | | | | | | | (18,004) |
| 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 on marketable securities | — | — | — | — | — | — | — | (51) | — | (51) |
| Net loss | — | — | — | — | — | — | — | — | (17,352) | (17,352) |
| Comprehensive loss | | | | | | | | | | (17,403) |
| Balances at December 31, 2003 (carried forward) | 39,514 | $ 83,635 | 1,884 | $ 2 | $ 12,762 | $ (4,677) | $ (654) | $ — | $ (79,365) | $ (71,932) |

**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 | | Common Stock | | Additional Paid-In Capital | Deferred Stock Compensation | Notes Receivable From Stockholders | Accumulated Other Comprehensive Income | Accumulated Deficit | Stockholders' Equity (Net Capital Deficiency) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Par Amount | | | | | | |
| Balances at December 31, 2003 (brought forward) | 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) |
| Balances at December 31, 2004 | — | $ — | 24,627 | $ 25 | $ 159,074 | $ (3,366) | $ (419) | $ (102) | $ (95,336) | $ 59,876 |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| **Operating activities** | | | |
| Net loss | $ (15,971) | $ (17,352) | $ (18,038) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 536 | 576 | 678 |
| Loss on disposal of property and equipment | 18 | 34 | 1 |
| Accretion and amortization on marketable securities | 361 | 581 | 329 |
| Interest accrued on notes receivable from stockholders | (37) | (40) | (46) |
| Amortization of stock-based compensation expense | 2,737 | 1,752 | 1,821 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (2,911) | (220) | 1,402 |
| Prepaid expenses and other current assets | 26 | (705) | (323) |
| Other assets | (384) | 33 | 3 |
| Accounts payable | (19) | 14 | 951 |
| Accrued liabilities | 1,312 | 921 | (438) |
| Deferred revenues | 7,000 | — | (339) |
| Net cash used in operating activities | (7,332) | (14,406) | (13,999) |
| **Investing activities** | | | |
| Purchases of marketable securities | (49,637) | (7,022) | (28,754) |
| Maturities and sales of marketable securities | 5,549 | 25,000 | 11,630 |
| Purchases of property and equipment | (1,863) | (138) | (469) |
| Net cash (used in) provided by investing activities | (45,951) | 17,840 | (17,593) |
| **Financing activities** | | | |
| Proceeds from issuance of ordinary shares in Dynavax Asia, net of issuance costs | — | 14,733 | — |
| Proceeds from issuance of preferred stock, net of issuance costs | — | — | 32,357 |
| Proceeds from issuance of common stock, net of issuance costs | 46,455 | 73 | 3 |
| Exercise of stock options | 16 | — | — |
| Proceeds from employee stock purchase plan | 70 | — | — |
| Repurchase of common stock | — | (43) | (65) |
| Repayment of notes receivable from stockholders | 272 | 100 | 136 |
| Restricted cash | (408) | — | — |
| Repayments of equipment financing | — | — | (15) |
| Net cash provided by financing activities | 46,405 | 14,863 | 32,416 |
| Net (decrease) increase in cash and cash equivalents | (6,878) | 18,297 | 824 |
| Cash and cash equivalents at beginning of year | 23,468 | 5,171 | 4,347 |
| Cash and cash equivalents at end of year | $ 16,590 | $ 23,468 | $ 5,171 |

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)**

**(In thousands)**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| **Supplemental disclosure of non-cash investing and financing activities** | | | |
| Lease incentive | $ 350 | $ — | $ — |
| Net unrealized (loss) gain on marketable securities | $ (102) | $ (51) | $ 34 |
| 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 | $ 65 |
| Interest accrued on notes receivable | $ 37 | $ 40 | $ 46 |
| Deemed dividend upon issuance of ordinary shares of Dynavax Asia | $ — | $ 633 | $ — |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Organization

Dynavax Technologies Corporation ("Dynavax", the "Company", "we" or "us") 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.

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. The effect of the reverse stock split is reflected in the Consolidated Financial Statements for all periods presented. As a result of the initial public offering, all outstanding shares of Preferred Stock converted to 13,712,128 shares of common stock.

### Subsidiaries

In October 2003, the Company formed Dynavax Asia Pte. Ltd. (Dynavax Asia), a 100% owned subsidiary in Singapore which focuses on the Company's clinical and preclinical hepatitis B programs. 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 became 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, the development of biopharmaceutical products.

Certain reclassifications of prior year amounts related to deferred revenue (current and long-term), research and development, and general and administrative expenses have been made to conform with the current year presentation. These reclassifications did not have a material impact on our financial position or results of operations.

### 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 could 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, no foreign currency translation adjustments or transaction gains or losses have been recorded as of December 31, 2004.

**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 FAS No. 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.

**Fair Value of Financial Instruments**

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

**Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that are subject to concentration of credit risk consist primarily of cash and cash equivalents, accounts receivable, and marketable securities. 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. The following table summarizes the revenues and accounts receivable balances from customers in excess of 10% of the total revenues or total accounts receivable balances, respectively:

| | Revenues | | | Accounts Receivable | |
|---|---|---|---|---|---|
| | Years Ended December 31, | | | December 31, | |
| Significant Customers | 2004 | 2003 | 2002 | 2004 | 2003 |
| A | — | — | 69% | — | — |
| B | — | — | 13% | — | — |
| C | — | — | 18% | — | — |
| D | 7% | 100% | — | 13% | 100% |
| E | 93% | — | — | 87% | — |

For the fiscal year ended December 31, 2004, the majority of our revenues and accounts receivable were derived from a collaboration agreement with UCB Farchim, SA (UCB) which ended in March 2005. The Company expects to collect 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.

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 lab equipment.

**Revenue Recognition**

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 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 Expense and Related Accruals**

Research and development expenditures are charged to operations as incurred. Research and development expense consists of direct and indirect internal costs related to specific functional areas and projects, as well as fees paid to contract research organizations, research institutions, contract manufacturing organizations, and other service providers which conduct certain research and development activities on behalf of the Company.

Preclinical and clinical studies are a significant component of research and development expense. We accrue costs related to clinical trials on a straight-line basis over the term of the service period based on our initial estimate that the work performed under the contracts occurs ratably over the periods to the expected milestone, event or total contract completion date. The estimates may or may not match the actual services performed by research institutions and contract research organizations that conduct and manage clinical trials on our behalf, as determined by patient enrollment levels and other measures of activities specified in the contract. As a result, we adjust our estimates at the end of each reporting period, if required, based on our ongoing review of the level of effort actually incurred by the organizations.

The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under these contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. 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, regardless of payment status.

**Stock-Based Compensation**

The Company has adopted the pro forma disclosure requirements of FAS No. 123, “Accounting for Stock-Based Compensation” as amended by FAS No. 148, “Accounting for Stock-Based Compensation — Transition and Disclosure.” As permitted under FAS No. 123, we continue to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by APB No. 25 and its interpretations. Under APB No. 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 FAS No. 123 to employee stock compensation (in thousands, except per share amounts):

| | Years ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Net loss attributable to common stockholders, as reported | $ (15,971) | $ (17,985) | $ (18,038) |
| Add: Stock-based employee compensation expense included in net loss | 2,170 | 1,752 | 1,821 |
| Less: Stock-based employee compensation expense determined under the fair value based method | (2,816) | (1,996) | (2,013) |
| Net loss attributable to common stockholders, pro forma | $ (16,617) | $ (18,229) | $ (18,230) |
| Net loss per share attributable to common stockholders: | | | |
| Basic and diluted, as reported | $ (0.75) | $ (10.04) | $ (10.65) |
| Basic and diluted, pro forma | $ (0.78) | $ (10.18) | $ (10.76) |

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:

| | Employee Stock Options | | | Employee Stock Purchase Plan |
|---|---|---|---|---|
| | 2004 | 2003 | 2002 | 2004 |
| Weighted-average fair value | $5.04 | $6.68 | $1.32 | $7.50 |
| Risk-free interest rate | 2.3% to 3.5% | 2.4% to 2.9% | 2.4% to 3.5% | 2.0% |
| Expected life (in years) | 4 | 4 | 4 | 0.5 |
| Volatility | 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 and losses on marketable securities in accumulated other comprehensive loss.

**Income Taxes**

We account for income taxes using the asset and liability method under FAS No. 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 December 16, 2004, the FASB issued FAS No. 123R (revised 2004), "Share-Based Payment," that requires all share-based payments to employees, including grants of employee stock options, to be recognized based on their fair values. Pro forma disclosure is no longer an alternative. FAS No. 123R supersedes APB No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows." Under FAS No. 123R, share-based payments 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. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Public companies are allowed to select from three alternative transition methods–each having different reporting implications. FAS No. 123R is effective for interim and annual periods beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date. Although we have elected to follow the intrinsic value method prescribed by APB No. 25 through the year ended December 31, 2004, we will adopt FAS No. 123R in 2005. The adoption of FAS No. 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because we are in the process of reevaluating our methodology used to determine fair value, including consideration of an option-pricing model and related assumptions. In addition, the impact of adoption will depend on levels of share-based payments granted in the future. However, we believe that had we adopted FAS No. 123R in prior periods using the Black-Scholes model, the impact of that standard could have approximated the impact as described in the disclosure of pro forma net loss and net loss per share in Note 1 to the Consolidated Financial Statements.

## 3. Marketable Securities

The following is a summary of available-for-sale securities as of December 31, 2004 and 2003 (in thousands):

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| **December 31, 2004:** | | | | |
| 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 |
| Total | $ 49,356 | $ 3 | $ (105) | $ 49,254 |
| | | | | |
| **December 31, 2003:** | | | | |
| Corporate debt securities | $ 5,629 | $ 1 | $ (1) | $ 5,629 |
| Total | $ 5,629 | $ 1 | $ (1) | $ 5,629 |

There were no realized gains from sales of marketable securities for the years ended December 31, 2004 and 2003. As of December 31, 2004 and 2003, 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, 2004, our marketable securities had the following maturities (in thousands):

| Maturities in: | Amortized Cost | Estimated Fair Value |
|---|---|---|
| 2005 | $ 45,015 | $ 44,931 |
| 2006 | 4,341 | 4,323 |
| Total | $ 49,356 | $ 49,254 |

## 4. Property and Equipment

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Laboratory equipment | $ 2,327 | $ 1,937 |
| Computer and equipment | 661 | 582 |
| Furniture and fixtures | 737 | 370 |
| Leasehold improvements | 1,220 | 298 |
| | 4,945 | 3,187 |
| Less accumulated depreciation and amortization | (2,480) | (2,359) |
| | $ 2,465 | $ 828 |

Depreciation and amortization expense on property and equipment was $0.5 million, $0.6 million and $0.7 million for the years ended December 31, 2004, 2003, and 2002, respectively.

## 5. Current Accrued Liabilities

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

| | December 31, 2004 | December 31, 2003 |
|---|---|---|
| Payroll and related expenses | $ 1,093 | $ 761 |
| Legal expenses | 422 | 323 |
| Third party scientific research expense | 1,607 | 1,587 |
| Other accrued liabilities | 1,249 | 318 |
| | $ 4,371 | $ 2,989 |

## 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. 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, 2004, 2003 and 2002, was $1.4 million, $0.6 million and $0.6 million, respectively. Deferred rent was $0.1 million as of December 31, 2004.

We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to the Company of $104,656 in 2004 and $339,990 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, 2004, excluding payments from the sublease agreement, are as follows (in thousands):

| **Year ending December 31,** | |
|---|---|
| 2005 | $ 1,649 |
| 2006 | 1,698 |
| 2007 | 1,749 |
| 2008 | 1,802 |
| 2009 | 1,225 |
| | $ 8,123 |

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, 2004 and is collateralized by a certificate of deposit which has been included in restricted cash in the Consolidated Balance Sheets as of 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, 2004, under the terms of an agreement with a contract research organization, we are obligated to make future payments as services are provided up to $3.0 million in 2005.

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, 2004.

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, 2004.

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

*UCB Farchim, S.A.*

In February 2004, the Company entered into an agreement with UCB Farchim, S.A., a subsidiary of UCB, S.A., or UCB, a publicly traded multi-national company based in Brussels, Belgium, in which the Company licensed the technology, know-how and preclinical and clinical data related to its AIC and grass allergy programs to UCB on an exclusive, worldwide basis. UCB was also granted an option to license the Company's peanut allergy program. According to terms of the agreement, the Company received an $8.0 million upfront payment. In addition, UCB agreed to fund continued research and development of the licensed programs.

In March 2005, Dynavax and UCB agreed to end their development and commercialization collaboration in seasonal allergy products. Under the terms of the agreement, UCB will return all rights to the allergy program to Dynavax and the current ongoing Phase II/ III clinical trial of our AIC immunotherapy will be completed as planned. Dynavax will assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to AIC and for preclinical development programs in grass and in peanut allergy. The Company expects to recognize all revenues and deferred revenues associated with UCB through the term of the agreement.

*University of California*

The Company entered into a series of exclusive license agreements with the Regents of the University of California 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. The Company incurred license fees of $20,000 in each of the fiscal years 2004, 2003 and 2002 and patent expenses of $0.5 million, $0.2 million, and $0.4 million in the years ended December 31, 2004, 2003, and 2002, respectively, in connection with these license agreements, all of which was recorded as research and development expense. The Company also incurred a $0.4 million one-time charge to UC due upon the closing of the Company's initial public offering as partial consideration for the

technology licenses. The Company recorded this charge as research and development expense in the first quarter of 2004. Also as partial consideration for the technology licenses, the Company incurred a one-time charge of $0.2 million to UC related to the $8.0 million upfront payment from UCB Farchim, SA discussed above.

In December 1998, the Company entered into a research agreement with UC to fund a research project on "Biological Effects of ISS and IIS-ODN." The principal investigator of the research project is one of the Company's founders and stockholders. The project commenced in January 1999 and continued through 2003. The Company agreed to fund and support future project costs of approximately $1.0 million per year, to a maximum aggregate amount of $4.9 million. In connection with this agreement, the Company incurred research and development expenses associated with the project of $0.7 million and $1.0 million during the years ended December 31, 2003 and 2002, respectively.

*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 for the achievement of a milestone and 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. The agreement may be terminated by either party. As of December 31, 2004, we recorded an accrual of $0.3 million associated with the achievement of the contractual milestone.

*Berna Biotech*

In October 2003, the Company entered into an agreement with Berna Biotech, a publicly traded company based in Bern, Switzerland, in which Berna agreed to supply the Company with its proprietary hepatitis B surface antigen for use in the Company's Phase III clinical trials for its hepatitis B vaccine and, if merited, its subsequent commercialization. According to terms of the agreement, the Company 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. Berna has agreed to purchase ISS at fixed amounts from the Company for the potential commercial vaccine, should Berna sell the vaccine commercially. The Company also agreed to make certain commercialization and sales milestone payments to Berna regarding the Company's hepatitis B vaccine. A non-refundable, non-creditable license fee of $0.5 million was made to Berna in November 2003. This amount was recorded as research and development expense in the fourth quarter of 2003. Under the terms of the agreement, Berna has an exclusive right to commercialize the hepatitis B vaccine under terms to be negotiated, but may choose to opt out of that right. Berna also agreed to supply its hepatitis B surface antigen for the Company's use in further developing the product candidate for hepatitis B therapy. Berna also received an option to collaborate with the Company in the development and commercialization of the Company's hepatitis B therapy product candidate. The agreement remains in effect for 15 years from the date of first commercial sale of the Company's hepatitis B vaccine, unless terminated sooner according to its terms.

*Other Agreements*

In December 1999, the Company entered into a two-year collaboration agreement with Aventis Pasteur S.A. ("Aventis") to develop new vaccines and therapeutic drugs for a variety of infectious diseases. Under this agreement, Aventis paid the Company for certain research to be completed pursuant to the terms of the agreement at a rate of cost plus 10%, with a maximum total cost of $1.5 million for the first product and an additional $0.6 million for the second product being developed. The Company received an upfront payment of $1.1 million, which was earned and recognized as revenue through December 31, 2001. During 2002, $1.0 million of revenue was recognized for completed collaboration work. The agreement was mutually terminated in September 2002.

In March 2000, the Company entered into an 18-month collaboration and license agreement with Triangle Pharmaceuticals Inc. ("Triangle Pharmaceuticals") to develop therapies for the treatment and prevention of hepatitis and HIV. Under this agreement, the Company licensed certain technology to Triangle Pharmaceuticals for its use in research and development activities. Additionally, Triangle Pharmaceuticals paid the Company to perform certain research and development activities and for the achievement of certain mutually agreed-upon milestones. During 2000, the Company recognized revenue of $0.3 million based on achievement of a milestone. During 2002, the Company recognized revenue of $0.2 million in relation to the collaboration and license agreement. The agreement was mutually terminated on November 25, 2002.

In the third quarter of 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. For the years ended December 31, 2004 and 2003, we recognized revenues of $1.0 million and $0.8 million, respectively. In the fourth quarter of 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.

## 8. 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, without consideration for dilutive potential common shares. 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 dilutive potential 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 dilutive potential common shares and are only included in the calculation of diluted net loss per share attributable to common stockholders when their effect is dilutive.

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| **Historical (in thousands, except per share amounts):** | | | |
| Numerator: | | | |
| Net loss attributable to common stockholders | $ (15,971) | $ (17,985) | $ (18,038) |
| Denominator: | | | |
| Weighted-average common shares outstanding | 21,200 | 1,849 | 1,886 |
| Less: Weighted-average unvested common shares subject to repurchase | (13) | (58) | (192) |
| Denominator for basic and diluted net loss per share attributable to common stockholders | 21,187 | 1,791 | 1,694 |
| Basic and diluted net loss per share attributable to common stockholders | $ (0.75) | $ (10.04) | $ (10.65) |
| | | | |
| **Historical outstanding dilutive securities not included in diluted net loss per share attributable to common stockholders calculation (in thousands):** | | | |
| Preferred stock | — | 15,823 | 13,612 |
| Options to purchase common stock | 1,828 | 1,334 | 691 |
| Warrants | 84 | 84 | 90 |
| | 1,912 | 17,241 | 14,393 |

## 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, decreased authorized preferred stock to 5,000,000 shares, provided for a temporary waiver of the Company's Series D convertible preferred stock IPO anti-dilution provisions, and required a vote of 66 2/3% of the then outstanding shares to amend the annual meeting and the special meeting provisions, to nominate directors, and to stagger the board structure.

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.

### Convertible Preferred Stock

As of December 31, 2003, the Company had authorized 61,767,098 shares of convertible preferred stock, designated in various series. The convertible preferred stock defined as Series A, Series B, Series C, Series D, Series E-1, Series E-2, Series S-1, Series R, and Series T are summarized as follows (in thousands, except per share amounts):

| | Shares Designated | Minimum Liquidation Preference Per Share | Shares Issued and Outstanding at December 31, 2003 |
|---|---|---|---|
| Series A | 6,700 | $ 1.00 | 6,700 |
| Series B | 9,033 | $ 1.83 | 9,033 |
| Series C | 5,669 | $ 4.00 | 5,669 |
| Series D | 17,135 | $ 2.06 | 16,882 |
| Series E-1 | 22,000 | $ 2.40 | — |
| Series S-1 | 400 | $ 5.00 | 400 |
| Series R | 430 | $ 4.65 | 430 |
| Series T | 400 | $ 5.00 | 400 |
| | 61,767 | | 39,514 |

*Voting*

The holders of convertible preferred stock have various rights and preferences. Each share of Series A, Series B, Series C, Series D, Series E-1, Series S-1, Series R, and Series T convertible preferred stock has voting rights equal to the number of shares of common stock into which it is convertible and votes together as one class with the common stock.

The vote of a majority of the holders of the Series A, Series B, Series C, Series D, Series E-1, Series S-1, Series R, and Series T convertible preferred stock is required for certain issuances of common stock, any redemption, repurchase, dividend, or other distribution with respect to the common stock, any agreement by the Company or its stockholders regarding certain mergers or consolidations of the Company and a sale of all or substantially all the assets of the Company, and any redemption, repurchase, dividend, or other distribution with respect to any shares of convertible preferred stock.

*Liquidation*

In the event of any liquidation, dissolution, or winding up of the Company, including a merger, acquisition, or sale of assets where the holders of the Company's common stock and convertible preferred stock own less than 51% of the resulting voting power of the surviving entity, the holders of the Series E-1

convertible preferred stock will receive, in preference to all other holders of equity securities, an amount per share equal to the original purchase price for the Series E-1, plus any accrued but unpaid dividends if such event occurs thereafter. After payment of the liquidation preference to the holders of Series E-1 convertible preferred stock, the holders of the Series D convertible preferred stock will receive, in preference to all other holders of equity securities, an amount per share equal to 2.0 times the original purchase price of $2.06 per share plus any accrued but unpaid dividends if such event occurs thereafter. After payment of the liquidation preference to the holders of Series D convertible preferred stock, the holders of all other convertible preferred stock are entitled to receive, prior and in preference to the holders of common stock, an amount equal to the original issue price ($1.00, $1.83, $4.00, $5.00, $4.65, and $5.00 for Series A, Series B, Series C, Series S-1, Series R, and Series T convertible preferred stock, respectively) plus any accrued but unpaid dividends. After payment of the liquidation preference to holders of all series of convertible preferred stock, the remaining assets of the Company are available for distribution on a pro rata (as-converted into common stock) basis to the holders of common stock and holders of Series A, Series B, Series D Preferred and Series E-1 convertible preferred stock. To the extent that holders of Series A, Series B, Series D, and Series E-1 have received an aggregate of $3.00, $5.49, $6.18 and three times the original purchase price for the Series E-1 convertible preferred stock, per share, respectively, any remaining assets will be additionally available for distribution solely to the holders of common stock.

*Conversion*

Each share of Series A, Series B, Series C, Series D, Series E-1, Series S-1, Series R, and Series T convertible preferred stock automatically converts at an initial rate of one share of common stock for one share of convertible preferred stock, adjusted for stock splits and certain other transactions, either i) at the affirmative election of the holders of at least 66²/₃% of the outstanding shares of convertible preferred stock voting as a single class (except for Series C, Series D, and Series E-1 which each shall convert on a vote of holders of at least 66²/₃%, 66²/₃%, and 51% of the outstanding shares of the respective series), or ii) at the closing of a public offering of common stock in which the price per share is equal to or greater than $4.12 per share and gross proceeds to the Company are at least $30 million. All of the shares of convertible preferred stock were converted into common shares upon the closing of the Company's initial public offering.

*Redemption Rights*

Neither the Company nor the holders of the convertible preferred stock have the right to call or redeem or cause to have called or redeemed any shares of convertible preferred stock, except that the Series E-2 convertible preferred stock is automatically redeemed and canceled by the Company upon the occurrence of certain events.

**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 from the date of the grant for five years and remained outstanding at December 31, 2004.

**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") under which 3,500,000 shares have been reserved and approved for issuance, 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. In addition, as part of the 2004 Plan, the Board of Directors and Stockholders adopted the 2004 Non-employee Director Option Program. The 2004 Plan became effective on February 11, 2004.

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.

Activity under our stock option plans is set forth below:

| | Options Available for Grant | Number of Options Outstanding | Weighted-Average Price Per Share |
|---|---|---|---|
| Balance at December 31, 2001 | 381,388 | 278,944 | $ 3.06 |
| Options granted | (458,933) | 458,933 | $ 2.16 |
| Options exercised | — | (3,820) | $ 0.84 |
| Options canceled | 42,850 | (42,850) | $ 3.00 |
| Shares repurchased | 57,476 | — | $ 1.14 |
| Balance at December 31, 2002 | 22,781 | 691,207 | $ 2.48 |
| Options authorized | 1,000,000 | — | — |
| Options granted | (828,500) | 828,500 | $ 2.34 |
| Options exercised | — | (54,708) | $ 1.34 |
| Options canceled | 131,000 | (131,000) | $ 2.38 |
| Shares repurchased | 19,715 | — | $ 2.21 |
| Balance at December 31, 2003 | 344,996 | 1,333,999 | $ 2.45 |
| Options authorized | 3,500,064 | — | — |
| Options granted | (513,847) | 513,847 | $ 5.06 |
| Options exercised | — | (7,769) | $ 2.34 |
| Options canceled | 12,081 | (12,081) | $ 3.81 |
| Shares repurchased | — | — | — |
| Balance at December 31, 2004 | 3,343,294 | 1,827,996 | $ 3.17 |

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 | 98,982 | 9.7 | $ 4.69 | — | — |
| $5.90 | 10,000 | 9.8 | $ 5.90 | — | — |
| $6.45 | 112,950 | 9.7 | $ 6.45 | 5,290 | $ 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 | 1,827,996 | 8.4 | $ 3.17 | 1,527,989 | $ 2.55 |

The following summarizes options outstanding and exercisable under our stock option plans as of December 31, 2003:

| 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 | 10,020 | 5.0 | $ 0.60 | 10,020 | $ 0.60 |
| $1.20 | 20,972 | 6.2 | $ 1.20 | 20,972 | $ 1.20 |
| $1.50 | 516,872 | 9.1 | $ 1.50 | 516,872 | $ 1.50 |
| $3.00 | 774,802 | 9.1 | $ 3.00 | 774,802 | $ 3.00 |
| $12.00 | 11,333 | 7.3 | $ 12.00 | 11,333 | $ 12.00 |
| $0.60-12.00 | 1,333,999 | 9.0 | $ 2.45 | 1,333,999 | $ 2.45 |

**Deferred Stock Compensation**

As of December 31, 2004, there was $3.4 million of deferred stock-based compensation remaining to be amortized in future periods in connection with the grant of stock options to employees and non-employees. Deferred stock compensation is amortized as a charge to operations using the straight-line method over the option vesting period, ranging up to 4 years. Employee and director stock-based compensation expense and non-employee stock-based compensation expense were as follows (in thousands):

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Employees and directors stock-based compensation expense | $ 2,170 | $ 1,752 | $ 1,821 |
| Non-employees stock-based compensation expense | 567 | — | — |
| Total | $ 2,737 | $ 1,752 | $ 1,821 |

**Employee Stock Purchase Plan**

In January 2004, the Board of Directors and Stockholders adopted the 2004 Employee Stock Purchase Plan (the “Purchase Plan”) under which 250,000 shares were reserved and approved for issuance, 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. 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). In 2004, employees acquired 12,697 shares of our common stock under the Purchase Plan. At December 31, 2004, 237,303 shares of our common stock remained available for future purchases under the Purchase Plan.

**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.

**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 are full recourse notes, which accrue interest at rates ranging from 5.02% to 6.22% and are due from September 2000 through June 2006. The shares of common stock held by the employees collateralize these notes. At December 31, 2004 and 2003, $0.4 million and $0.7 million, respectively, remained outstanding.

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 460,119 shares of the Company's common stock as of December 31, 2004. Dr. Carson also received payments of $35,000 in 2004 and 2003 for consulting services provided to the Company .

**12. Income Taxes**

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| **Deferred tax assets:** | | |
| Net operating loss carry forwards | $ 17,339 | $ 14,385 |
| Research tax credit carry forwards | 1,587 | 1,436 |
| Accruals and reserves | 4,695 | 1,315 |
| Capitalized research costs | 11,020 | 12,365 |
| Other | 232 | 187 |
| Total deferred tax assets | 34,873 | 29,688 |
| Less valuation allowance | (34,873) | (29,688) |
| | $ — | $ — |

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, 2004 and 2003. The valuation allowance increased $5.2 million and $6.5 million during the years ended December 31, 2004 and 2003, respectively.

As of December 31, 2004, the Company had federal net operating loss carryforwards of approximately $45.0 million, which expire at various dates from 2011 through 2024, and federal research and development tax credits of approximately $1.0 million, which expire at various dates from 2018 through 2024 if not utilized.

As of December 31, 2004, the Company had California state net operating loss carryforwards of approximately $32.0 million, which expire at various dates from 2006 through 2014, and California state research and development tax credits of approximately $1.0 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited.

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

| | Year Ended December 31, 2004 | | | | Year Ended December 31, 2003 | | | |
|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Revenues | $ 3,205 | $ 5,492 | $ 3,660 | $ 2,455 | $ — | $ 96 | $ 23 | $ 707 |
| Net loss attributable to common stockholders | $ (3,866) | $ (2,909) | $ (4,033) | $ (5,163) | $ (4,718) | $ (3,955) | $ (4,139) | $ (5,173) |
| Basic and diluted net loss per share attributable to common stockholders | $ (0.36) | $ (0.12) | $ (0.16) | $ (0.21) | $ (2.68) | $ (2.23) | $ (2.30) | $ (2.83) |
| Weighted-average shares used in computing basic and diluted net loss per share attributable to common stockholders(1) | 10,847 | 24,594 | 24,609 | 24,622 | 1,759 | 1,776 | 1,803 | 1,827 |

(1) The weighted-average shares increased from the fourth quarter 2003 to the first quarter 2004 due to the issuance of common stock, conversion of preferred stock, and conversion of ordinary shares in Dynavax Asia resulting from our initial public offering 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.

## 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

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and CFO concluded that the Company's 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")) as of the end of period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

### (b) Changes in internal controls

William J. Dawson, the former Vice President, Finance & Operations and Chief Financial Officer, resigned in June 2004 and remained a consultant to the Company through the date of his replacement. Timothy G. Henn was appointed Vice President, Finance and Administration in August 2004 and Chief Accounting Officer in January 2005. Also during the third quarter 2004, Dino Dina, President and Chief Executive Officer, assumed the role of Acting Chief Financial Officer. Deborah A. Smeltzer was appointed Vice President, Operations and Chief Financial Officer in January 2005. No other changes in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

On January 20, 2005 the Compensation Committee of the Board of Directors of the Company took action with respect to the compensation of the Company's named executive officers (determined by reference to the Company's proxy statement dated May 14, 2004), including the establishment of base salaries for 2005, approval for payment of bonus amounts in 2005 based primarily on the achievement of specified 2004 corporate and individual goals, and approval of annual stock option awards. The base salaries, bonus amounts and stock option awards, including a summary of the terms of the compensation arrangements under which they are or were to be paid, are set forth in Exhibit 10.18 to this Form 10-K.

## 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 2005 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, 2004.

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

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 RELATIONSHIP 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 ACCOUNTING FEES AND SERVICES

Information required by this Item is incorporated by reference to the section entitled “Audit Fees” in the Proxy Statement.

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

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

**1. Financial Statements**

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

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 Schedule**

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

**(b) Reports on Form 8-K**

| Date | Item Reported |
|---|---|
| November 8, 2004 | We filed a Current Report on Form 8-K on November 8, 2004, furnishing under Item 12, our press release announcing our financial results for the third quarter ended September 30, 2004. |

**(c) Exhibits**

| Exhibit Number | Document |
|---|---|
| 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. |
| 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 |

| Exhibit Number | Document |
|---|---|
| 10.17** | Management Continuity and Severance Agreement, dated as of August 27, 2004, between Dynavax Technologies Corporation and Timothy Henn |
| 10.18*** | Compensation Arrangements with Named Executive Officers |
| 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 Report of Form 8-K, dated August 23, 2004

*** Filed herewith

† 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

## SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

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

Dino Dina, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 18, 2005

By: /s/ DEBORAH A. SMELTZER

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

Date: March 18, 2005

By: /s/ TIMOTHY G. HENN

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

Date: March 18, 2005

## POWER OF ATTORNEY

Each person whose signature appears below constitutes Dino Dina, M.D. and Deborah A. Smeltzer his or her true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, each acting alone, or his or her substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Dino Dina, M.D.<br>Dino Dina, M.D. | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 18, 2005 |
| /s/ Deborah A. Smeltzer<br>Deborah A. Smeltzer | Vice President, Operations and Chief Financial Officer<br>*(Principal Financial Officer)* | March 18, 2005 |
| /s/ Timothy G. Henn<br>Timothy G. Henn | Vice President, Finance & Administration and Chief Accounting Officer<br>*(Principal Accounting Officer)* | March 18, 2005 |
| /s/ Daniel S. Janney<br>Daniel S. Janney | Chairman of the Board | March 18, 2005 |
| /s/ Louis C. Bock<br>Louis C. Bock | Director | March 18, 2005 |
| /s/ Dennis Carson, M.D.<br>Dennis Carson, M.D. | Director | March 18, 2005 |
| /s/ Jan Leschly<br>Jan Leschly | Director | March 18, 2005 |
| /s/ Arnold Oronsky, Ph.D.<br>Arnold Oronsky, Ph.D. | Director | March 18, 2005 |
| /s/ Denise M. Gilbert, Ph.D.<br>Denise M. Gilbert, Ph.D. | Director | March 18, 2005 |

Exhibit 10.18

**COMPENSATION ARRANGEMENTS WITH NAMED EXECUTIVE OFFICERS**

Named executive officers are compensated under arrangements providing for employment at will and are also parties to Management Continuity and Severance Agreements previously filed.

| Name | Base Salary (effective 1/1/05) | Bonus Amount Paid in 2005 | 2005 Stock Option Award |
|---|---|---|---|
| Dino Dina | $ 338,000 | $ 130,000 | 50,000 shares |
| Bob Coffman | $ 250,000 | $ 96,000 | 75,000 shares |
| Dan Levitt | $ 260,000 | $ 41,667(1) | 50,000 shares |
| Deborah Smeltzer | $ 260,000 | Not applicable(2) | No grant(3) |
| Stephen Tuck | $ 221,000 | $ 85,000 | 50,000 shares |
| Gary Van Nest | $ 221,000 | $ 63,750 | 25,000 shares |

The stock options granted to the named executive officers by the Compensation Committee were granted on January 20, 2005. The stock options have an exercise price per share of $7.49, which was the fair market value at the time of the grant. Each executive officer's stock options listed above will vest on an equal monthly basis over a four-year period.

(1) Excludes $58,333 paid as a guaranteed bonus in 2004.

(2) Deborah Smeltzer joined the Company on January 4, 2005 as Vice President, Operations and Chief Financial Officer and was not eligible for a bonus related to 2004 activities but received a signing bonus of $50,000.

(3) Deborah Smeltzer did not receive an annual option grant for 2005; rather she received two option grants at her hiring date of January 4, 2005 totaling 225,000 shares with an exercise price of $7.32, which was the fair market value at the time of the grant. The first option for 200,000 shares vests as to one-quarter of all underlying shares at the one-year anniversary of her grant and 1/48th of all underlying shares on a monthly basis thereafter. The second option for 25,000 shares vests upon the achievement of a specified milestone.

Exhibit 21.1

**List of Subsidiaries**

Dynavax Asia Pte. Ltd.
Ryden Therapeutics KK

Exhibit 23.1

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-113220) of Dynavax Technologies Corporation pertaining to the 1997 Equity Incentive Plan, the 2004 Stock Incentive Plan and the 2004 Employee Stock Purchase Plan of Dynavax Technologies Corporation of our report dated February 4, 2005 except for the second paragraph of Note 7 as to which the date is March 18, 2005, with respect to the Consolidated Financial Statements of Dynavax Technologies Corporation included in the Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 18, 2005

Exhibit 31.1

**Rule 13a-14(a) Certification of Chief Executive Officer**

CERTIFICATIONS

I, Dino Dina, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably like to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Dino Dina, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 18, 2005

Exhibit 31.2

**Rule 13a-14(a) Certification of Chief Financial Officer**

CERTIFICATIONS

I, Deborah A. Smeltzer, certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
    b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
    d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably like to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
    a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ DEBORAH A. SMELTZER

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

Date: March 18, 2005

Exhibit 32.1

**Certification Pursuant to Section 1350 of Chapter 63**
**of Title 18 of the United States Code**

I, Dino Dina, M.D., hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

(i) The Annual Report of the Company on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and

(ii) The information contained in the Report fairly represents, in all material respects, the financial condition and results of operations of the Company.

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

Dino Dina, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 18, 2005

Exhibit 32.2

**Certification Pursuant to Section 1350 of Chapter 63**
**of Title 18 of the United States Code**

I, Deborah A. Smeltzer, hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

(i) The Annual Report of the Company on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and

(ii) The information contained in the Report fairly represents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ DEBORAH A. SMELTZER

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

Date: March 18, 2005