DYNAVAX TECHNOLOGIES CORP

FORM 10-K
(Annual Report)

Filed 3/30/2004 For Period Ending 12/31/2003

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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, 2003

or

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

For the transition period from to .

Commission file number: 000-24647

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

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

717 Potter Street, Suite 100
Berkeley, CA 94710-2722
(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 ☑

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 ☐ 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 February 27, 2004 as reported on the Nasdaq National Market, was approximately $67,457,073.60. 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 27, 2004, registrant had outstanding 24,607,835 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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DYNAVAX TECHNOLOGIES CORPORATION

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This 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 the safe harbor created by those sections. These forward-looking statements include, but are not limited to: 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 on our recognition of revenue, uncertainty regarding our future operating results and our profitability, anticipated sources of funds and all plans, objectives, expectations and intentions contained in this report that are not historical facts. We usually use words such as may, will, should, expect, plan, anticipate, believe, estimate, predict, future, intend, or certain or the negative of these terms or similar expressions to identify forward-looking statements. Discussions containing such forward-looking statements may be found throughout the document. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. We disclaim any obligation to update these forward-looking statements as a result of subsequent events. The business risks discussed in Item 7 of this Report on Form 10-K, among other things, should be considered in evaluating our prospects and future financial performance.

PART I

ITEM 1. BUSINESS

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. Based on results from Phase II trials for our two lead product candidates, we plan to initiate Phase III trials in 2004. In addition, we have a third product candidate in Phase II trials. We also have a number of earlier stage clinical and preclinical programs.

Our most advanced clinical programs 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 several Phase II trials in the U.S., Canada and France. Results from completed Phase I and Phase II trials demonstrated AIC provided measurable clinical improvement and was well tolerated. We are currently conducting a two-year, multi-site Phase IIb trial in the U.S. to evaluate the efficacy of AIC, and began enrolling patients in the first quarter of 2004. We anticipate that data from this study, in conjunction with data from a confirmatory Phase III trial to start later in 2004 and focused on the 2005 ragweed season, will support a Biologics License Application, or BLA, filing.

- *Hepatitis B Prophylaxis.* We are nearing completion of two Phase II trials in Canada for our hepatitis B vaccine. In these trials our hepatitis B vaccine induced more rapid immunity with fewer immunizations than currently available vaccines. As a result, 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. We are currently planning to initiate

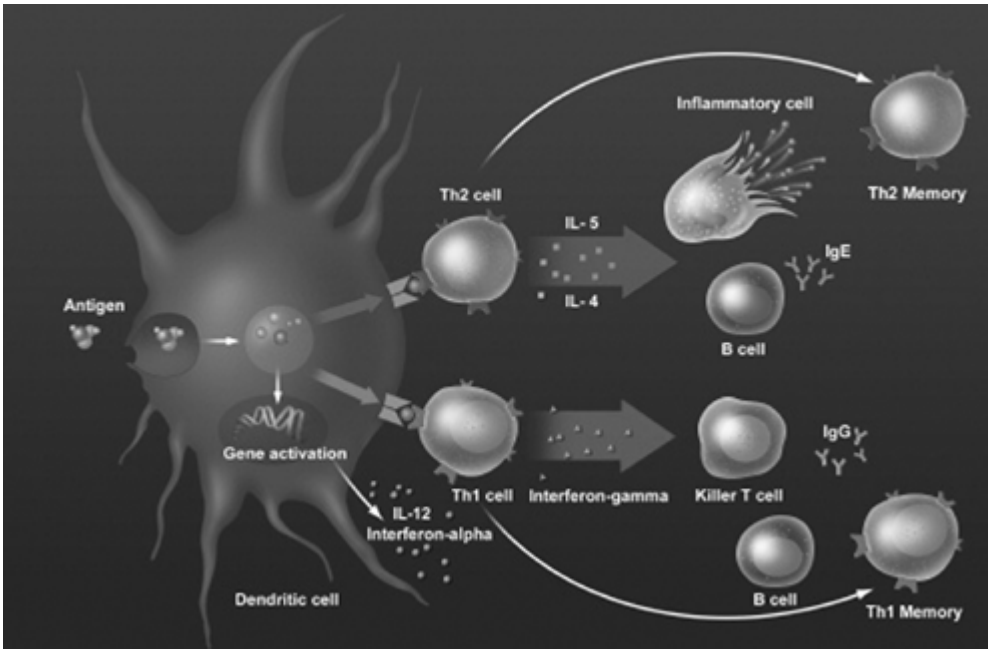
Phase III trials outside the U.S. in 2004. Foreign regulatory agencies may require us to conduct additional clinical trials prior to approval.

- *Asthma.* We have an inhaled therapeutic product candidate for asthma in a pilot Phase II 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. We expect results from our pilot Phase II trial in the summer of 2004.

We have an ISS-based cancer therapeutic product in Phase I trials and preclinical programs targeting additional allergies using our ISS technology. We have other preclinical programs focused on chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies.

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, which we call 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, asthma and cancer. To date, we have administered 1018 ISS to more than 350 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 clinical trials. Our principal programs are:

Allergy Immunotherapy

Ragweed Allergy

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. Many of these individuals experience allergies from more than one seasonal allergen, including ragweed, grasses and trees. The direct costs of prescription and over-the-counter, or OTC, interventions for allergic rhinitis in the U.S. is estimated to exceed $7.0 billion. In addition, approximately 20% of those who suffer from allergic rhinitis progress to asthma, leading to increased morbidity and disease management costs. Of the approximately 30 million people in the U.S. who suffer from ragweed allergy, a portion receive conventional immunotherapy each year. We believe a more substantial number take multiple prescription and OTC remedies. We believe these population segments constitute the primary target markets for the adoption of AIC.

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 to 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.

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 ten Phase I and Phase II trials in the U.S., France and Canada, with more than 175 people receiving over 1,350 AIC injections. 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 have initiated a two-year multi-site Phase IIb trial in the U.S. to evaluate the efficacy of AIC and begun enrolling patients in the first quarter of 2004. We anticipate that data from this study, in conjunction with data from a confirmatory Phase III trial to start later in 2004 and focused on the 2005 ragweed season, will support a BLA filing.

A Phase I trial, completed in the U.S. at Johns Hopkins University, suggested that AIC was better tolerated than conventional ragweed pollen extracts currently used in immunotherapy. This trial compared the skin test responses of six subjects receiving AIC and a commercially available ragweed immunotherapy product. The local allergic response to AIC was significantly less pronounced than that of the ragweed product. On average, approximately 180-fold more AIC was required to induce an allergic response equal to that of the ragweed product. These data support the potential for improved safety of AIC over ragweed extract for immunotherapy.

We conducted a Phase II trial in the U.S. in collaboration with Johns Hopkins University and the National Institutes of Health-sponsored Immune Tolerance Network. In the first year of the trial, 25 subjects were enrolled, 14 of whom received AIC and 11 of whom received placebo. Those receiving AIC were given a series of six weekly escalating doses of AIC ranging from 0.06 to 12.0 micrograms. All patients were treated prior to the 2001 ragweed season and then followed for symptoms during the season. Patients who received AIC therapy prior to the 2001 ragweed season had significantly lower nasal allergy symptoms and used less allergy medication during the 2001 season as compared to placebo. Patients were followed without further treatment during the 2002 ragweed season and results indicated the same level of efficacy. A statistically significant difference between AIC and placebo was observed in both years. Although the trial was small, these results suggest that a single six-injection course of AIC could provide protection against ragweed allergy that lasts for at least two allergy seasons.

We conducted a Phase II trial with similar design in Canada during the 2001 ragweed season. The primary endpoint of this trial was to examine the impact of AIC treatment on biological indicators of allergic response. In this trial, 28 subjects received AIC and 29 received placebo. After receiving the same dosage regimen as in the Phase II trial at Johns Hopkins University, patients were followed during the 2001 and 2002 ragweed seasons. With data from the 2001 ragweed season, this trial achieved a statistically significant increase in the number of Th2 cells secreting interferon-gamma, as well as a statistically significant decrease in the number of inflammatory cells, called eosinophils, and in the number of Th2 cells producing the inflammatory cytokine, IL-4. In addition, a strong trend towards a reduced number of Th2 cells secreting the inflammatory cytokine, IL-5, was also observed. These results indicated a shift away from a Th2 response towards a Th1 response. Although this trial met its primary endpoints, there was no impact on clinical symptom scores or medication use in 2001. We believe this result may have been due to more relaxed inclusion criteria, which resulted in the enrollment of patients without significant ragweed allergies. Clinical symptoms were impacted positively by AIC immunotherapy in 2002 and reached statistical significance for a subset of symptoms.

Three Phase II trials were also performed in France to evaluate the safety, tolerability and preliminary activity of higher doses of AIC, as well as the safety, tolerability and preliminary activity of re-immunizing patients with AIC prior to a second ragweed season. Across all three trials, 134 patients were enrolled, 67 of whom received an AIC regimen of up to 30 micrograms. Data are currently being analyzed, but preliminary assessments suggest that AIC was safely administered at these higher doses. No systemic adverse reactions were associated with treatment, and local reactions were mild and did not result in dose reductions.

We initiated a multi-site Phase IIb trial in the U.S. in the first quarter of 2004. We plan to enroll up to 462 eligible patients. Prior to the 2004 ragweed season, patients will receive 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 will be the change in nasal symptoms relative to placebo following the 2005 ragweed season.

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, 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 chooses pharmacotherapies over existing immunotherapies.

Peanut Allergy

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, with an estimated 50 to 100 deaths occurring 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 carefully monitor 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. A clinical trial conducted by an academic research institution that attempted to desensitize patients with peanut allergy through conventional immunotherapy was halted due to the occurrence of a serious adverse event.

Our Approach to the Treatment of Peanut Allergy and its Benefits

We believe that ISS linked with the principal 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 primary 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 the 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 much 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 peanuts. 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.

License and Development Agreement with UCB

In February 2004 we entered into an agreement with UCB Farchim, S.A., a subsidiary of UCB, S.A., a publicly traded multi-national company based in Brussels, Belgium, 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. UCB was also granted an option to license our peanut allergy program. According to the terms of the agreement, we received an upfront payment of $8 million and may earn additional payments based on achieving defined clinical and regulatory milestones of up to $40 million. In addition, UCB is obligated to fund substantially all of the continued research and development of the licensed programs, as well as costs relating to regulatory filings and potential product launch, sales and marketing. If any of the licensed product candidates is successfully developed and approved for sale, we will receive royalties on sales. We have retained an option to co-promote any approved product in the U.S. under specified circumstances. If this option were exercised, we would recognize revenue from product sales in lieu of receiving royalty payments in the United States. UCB may terminate the agreement at any time on 60 days' advance notice either in its entirety or with respect to one or more licensed programs, but may not terminate the agreement as to our ragweed allergy program prior to February 2006 except for safety or efficacy reasons, in which case it may not terminate the agreement prior to February 2005. Either party may terminate the UCB agreement if a default occurs and is not cured. Otherwise, the agreement does not terminate until the later to occur of the date when the last valid issued patent claim covering any of the licensed programs expires or June 2018.

Hepatitis B Products

Hepatitis B Prevention

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 recently 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 in 2001 exceeded $1.0 billion globally. If our hepatitis B vaccine product candidate is approved, we plan to introduce it in various markets outside the U.S. We cannot distribute this product in the U.S. due to the presence of third-party patents covering hepatitis B surface antigen in the U.S. that extend to as late as 2019.

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 approxi-

mately 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, only 53% of those who received the first dose of vaccine received the second dose of vaccine and only 30% received the third. We believe that compliance rates in other countries are similar. 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. Factoring together published clinical efficacy with compliance data, we estimate "field efficacy" of current vaccines to be approximately 50%. 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.

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

We intend to initiate international multi-site Phase III trials in 2004 with primary endpoints of protective hepatitis B antibody responses after each injection. Results from Phase I and interim results from Phase II trials showed that our vaccine candidate was well tolerated and induced more rapid immunity with fewer immunizations than other currently available vaccines. 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 are currently conducting 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 a commercially available vaccine, Engerix-B®. A total of 97 healthy young adults have been enrolled in this study, randomized to our vaccine and Engerix-B®. Interim results show that our vaccine induces a 77% rate of protective hepatitis B antibody response after one injection and 100% protective hepatitis B antibody responses after the second injection at two months. In contrast, subjects receiving Engerix-B® had rates of protective hepatitis B antibody responses after the first and second injections of 9% and 62%, respectively. We are also conducting a second Phase II trial to evaluate the efficacy of our vaccine in subjects who fail to respond to a full course of Engerix-B®.

Hepatitis B Therapy

Commercial Opportunity

Management of hepatitis B infection is a large and costly problem. Hepatitis B infection causes major morbidity, including acute and chronic inflammatory liver disease, which in turn can lead to cirrhosis, liver cancer and death. We believe a significant market opportunity exists in foreign markets, particularly in South- East Asia and the Pacific Basin (excluding Japan, Australia and New Zealand), where the World Health Organization estimates that 8% to 20% of people are chronic carriers of hepatitis B. Approximately 25% of chronic carriers develop serious liver disease, which needs to be medically managed.

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.

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 and primates 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.

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 without charge 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. We also agreed to make certain commercialization and sales milestone payments to Berna regarding our hepatitis B vaccine. 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 our use in further developing our product candidate for hepatitis B therapy. Berna also received an option to collaborate with us in the development and commercialization of our hepatitis B therapy product candidate. Berna may terminate the agreement if we fail to make required royalty payments, engage in unauthorized promotion of our hepatitis B vaccine, distribute hepatitis B surface antigen supplied to us by Berna without prior authorization from Berna, or fail to maintain customary levels of commercial liability insurance, and we do not correct the failure after a cure period.

Dynavax Asia

In October 2003 we formed Dynavax Asia Pte. Ltd., or Dynavax Asia, which will focus on our clinical and preclinical hepatitis B programs. Dynavax Asia is incorporated in Singapore and is a wholly owned subsidiary. We raised $15.2 million in gross proceeds from eight institutional investors to fund the operations of Dynavax Asia. Because of the high incidence of hepatitis B in Asia, we intend to conduct the majority of our Phase III trials for our hepatitis B vaccine product candidate there. We also intend to continue preclinical research and, if merited, early human clinical trials for our hepatitis B immunotherapy product candidate in Asia. We anticipate that certain activities associated with the conduct of these trials, as well as preclinical research into the development of advanced ISS formulations, will occur in Singapore. We will support the activities of Dynavax Asia through our own personnel and through limited hiring in Singapore.

Chronic Inflammation

Asthma

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 100 million individuals worldwide. In the U.S. alone, asthma is estimated to afflict 20 million people. In addition, cases of asthma are on the rise. Sales of asthma drugs worldwide exceeded $7.0 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 steroid hormones, called corticosteroids, either systemically or by inhalation. When administered as a drug, corticosteroids are known to 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. In addition, inhaled corticosteroids are associated with side effects such as reduced growth rate in children and possible bone demineralization. Other approaches block symptoms caused by inflammatory molecules, called leukotrienes, or prevent the release of histamines by blocking IgE antibodies, but both have modest efficacy.

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 on a weekly basis initially. 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

Based on preclinical studies that demonstrated efficacy in mouse and primate asthma models, we have initiated a clinical development program for inhaled 1018 ISS in asthma. We have completed 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 are currently conducting a pilot Phase II trial 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, 30 patients are being given four weekly doses of either 1018 ISS or placebo. The primary endpoint of this trial is a comparison of the allergen-induced clinical symptoms between 1018 ISS and placebo following the final dose. Results from this trial are expected in mid-2004.

Additional Programs

In addition to our primary product portfolio, we are pursuing the following earlier stage programs:

Next-Generation Vaccines

Anthrax

The demand for a new anthrax vaccine was heightened by the bioterrorist attacks in 2001, when anthrax-laden envelopes were sent via the U.S. Mail. 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.

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. 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 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 35 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 have used 1018 ISS in preclinical studies in conjunction with a variety of anti-tumor monoclonal antibodies as a combination therapy, with the goal of enhancing the cytotoxic effects that these antibodies have on cancer cells. This intervention has been shown to be effective in preclinical models utilizing anticancer monoclonal antibodies. We are currently conducting an open-label Phase I, dose-escalation trial of 1018 ISS in combination with Rituxan® in 26 patients with a cancer of the blood called non-Hodgkin’s lymphoma to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of 1018 ISS administered in combination with Rituxan®. We expect to complete the trial in 2004.

Antiviral Applications

The potential of natural or laboratory-engineered infectious microorganisms as weapons of terrorism and warfare is now recognized as a significant threat. In addition, naturally emerging infectious diseases are a

constant threat and impossible to anticipate. Vaccination against a few of these organisms, such as anthrax and smallpox, is possible; however, predicting all possible biological threats is impractical. 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.

We have contracted with BioSeek, Inc. to conduct preclinical studies to determine the mechanism of action for TZPs. Under the terms of the agreement, we are obligated to pay BioSeek a milestone payment upon determination of the mechanism of action. Additional milestone payments and royalties are payable to BioSeek if we partner or commercialize our TZP program.

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 ten issued U.S. and foreign patents, 33 pending U.S. patent applications, and 82 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 eight issued U.S. and foreign patents and eight pending U.S. and foreign patent applications providing worldwide rights to a group of small-molecule TNF-alpha synthesis inhibitors known as 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 14 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. 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 IIb clinical trial. 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 partners to help us market certain product candidates, such as UCB for our AIC and grass allergy product candidates and Berna Biotech for our hepatitis B product candidates. Although we have not yet determined our commercialization strategy for our other product candidates, we are inclined to license commercial rights to large pharmaceutical 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. In addition, 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 as indirect competition for AIC because they are targeting the same disease, although they do not attempt to treat the underlying causation 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 those manufactured by Roche Group, Schering-Plough Corporation, Gilead Sciences, Inc. and GlaxoSmithKline Plc.

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, or 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. Many new drugs that have shown promising results in early clinical trials subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. 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 27, 2004, we had 44 full-time employees, including nine Ph.D.s, two M.D.s and nine others with advanced degrees. Of the 44 employees, 32 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.

Risk Factors

Various discussions in this Annual Report on Form 10-K contain forward-looking statements concerning our future products, expenses, revenue, 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. Before 2003, almost all of our revenue resulted from payments made under collaboration agreements that have since lapsed or been mutually terminated. Currently, all of our revenue results from payments received under various government grant programs. These 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 approximately $79.4 million as of December 31, 2003, 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. We expect to begin Phase IIb and Phase III trials for AIC, an immunotherapy for ragweed allergy and Phase III trials for our hepatitis B vaccine in 2004. Our product candidates may never be commercialized, and we may never generate product-related revenue. Our ability to generate 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 sufficient to meet our anticipated cash requirements for at least the next 36 months. We do not believe that we will have product revenue until 2007, at the earliest. Because of the significant time and resources it will take to develop our product candidates, potentially commercialize them and generate revenue, 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 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, eliminate or divest one or more 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 Food and Drug Administration, or 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 only 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. In particular, in one of our Phase II trials for AIC, which was conducted in Canada in 2001 and 2002, there was no impact on clinical symptom scores or medication use in the first year of the two-year trial. 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 IIb trial in the first quarter of 2004 in the U.S. for AIC. We expect to begin planning later in 2004 a confirmatory Phase III trial for AIC, which will focus on the 2005 ragweed season. We also expect to initiate Phase III trials in 2004 for our hepatitis B vaccine outside the U.S. 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 revenue 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 revenue.

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 or our hepatitis B vaccine 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; 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 withdrawn 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 revenue 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. Currently we have established two collaborative relationships, one with Berna Biotech for our hepatitis B vaccine and hepatitis B therapeutic product candidates and the second with UCB Farchim, S.A., or UCB, for AIC and grass allergy immunotherapy. 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 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 is 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 only sufficient for us to conduct the two-year Phase IIb clinical trial we initiated in February 2004. 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 IIb and planned Phase III clinical trials for AIC and Phase 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 revenue.

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 revenue, if any.

We do not anticipate that any of our product candidates will be commercially available until 2007, 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 revenue 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 revenue 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, steroid hormones called corticosteroids and anti-leukotriene agents, which block symptoms caused by inflammatory molecules, 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 currently intend to conduct certain operations relating to our hepatitis B vaccine and therapeutic product candidates through Dynavax Asia Pte. Ltd., or Dynavax Asia, our subsidiary based in Singapore. We intend to commercialize our hepatitis B vaccine only outside the U.S. due to the presence of third-party patents in the U.S. covering hepatitis B surface antigen, a key component of our hepatitis B vaccine, that extend until as late as 2019. 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 revenue.

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 revenue 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. 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;
- 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;
- 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 you and other 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 43.46% of our outstanding common stock as of February 27, 2004. 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. See Management and Principal Stockholders for details on our capital stock ownership.

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.

ITEM 2. PROPERTIES

We lease approximately 11,500 square feet of laboratory and office space in Berkeley, California under a lease expiring in May 2008 and 8,700 square feet of general office space in Emeryville, California under a lease expiring in March 2004. In January 2004, we entered into a 10-year lease for approximately 20,500 square feet of laboratory and office space in Berkeley, California expiring in March 2014 to replace our Emeryville lease and provide for additional space.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

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 National 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. On February 27, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $8.40 per share.

	Common Stock Price	
	High	**Low**
February 19, 2004 through February 27, 2004	**$9.98**	**$8.04**

As of February 27, 2004, there were approximately 164 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.

Recent Sales of Unregistered Securities

During the past three years, the registrant has issued and sold the following unregistered securities:

(1) The Registrant granted 1,645,567 shares of restricted common stock and options to purchase shares of common stock at prices ranging from $1.50 to $12.00 to employees, directors and consultants pursuant to its 1997 Equity Incentive Plan. These issuances were made in reliance on Rule 701 of the Securities Act.

(2) From March 2002 to July 2002, the Registrant issued and sold an aggregate of 16,882,220 shares of its Series D Preferred Stock to a total of 46 investors for an aggregate purchase price of $34,777,373.20. These sales were made in reliance on Section 4(2) of the Securities Act.

(3) In August 2002, the Registrant issued a warrant to purchase 253,233 shares of its Series D Preferred Stock to Banc of America Securities LLC as placement agent in connection with the Series D financing. The warrant was issued in reliance on Section 4(2) of the Securities Act.

(4) In October 2003, Dynavax Asia Pte. Ltd., a subsidiary of the Registrant incorporated under the laws of Singapore, issued and sold an aggregate of 15,200,000 ordinary shares to a total of eight investors for an aggregate purchase price of $15,200,000. The ordinary shares will be exchanged for 2,111,111 shares of common stock of the Registrant upon the completion of this offering. These sales were made in reliance on Section 4(2) of the Securities Act.

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 $46.6 million. These proceeds are net of $3.6 million in underwriting discounts and commissions, $1.2 million in legal, accounting and printing fees and $0.3 million in other expenses. We used $125,000 of the net proceeds to make a one-time cash payment to the University of California pursuant to the terms of several license agreements with them. We intend to use the remaining net proceeds for general corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA

The following tables contain selected financial data as of and for each of the five years ended December 31, 2003, 2002, 2001, 2000, and 1999 and are derived from our financial statements. The selected financial data are qualified by reference to, and should be read in conjunction with, our financial statements and the notes to those financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended December 31,				
	2003	2002	2001	2000	1999
	(in thousands, except per share data)				
Consolidated statements of operations data:					
Collaboration and grant revenue	$ 826	$ 1,427	$ 2,359	$ 2,054	$ 450
Operating expenses:					
Research and development	14,381	15,965	17,363	8,267	6,049
General and administrative	4,209	4,121	4,527	3,451	1,396
Total operating expenses	18,590	20,086	21,890	11,718	7,445
Loss from operations	(17,764)	(18,659)	(19,531)	(9,664)	(6,995)
Interest income, net	412	621	1,119	1,149	436
Net loss attributable to common stockholders	$(17,985)	$(18,038)	$(18,412)	$(26,724)	$(6,559)
Basic and diluted net loss per share attributable to common stockholders	$ (10.04)	$ (10.65)	$ (12.29)	$ (22.59)	$ (7.72)
Shares used in computing basic and diluted net loss per share attributable to common stockholders (3)	1,791	1,694	1,498	1,183	850

	December 31,				
	2003	2002	2001	2000	1999
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 29,097	$ 29,410	$ 11,757	$ 26,792	$ 8,479
Working capital	25,590	25,913	9,498	26,578	6,634
Total assets	31,585	31,478	15,117	29,590	9,622
Equipment financing, net of current portion	—	—	—	15	167
Minority interest in Dynavax Asia	14,733	—	—	—	—
Mandatorily redeemable convertible preferred stock	—	—	45,479	45,486	24,079
Convertible preferred stock	83,635	83,635	5,799	5,799	—
Accumulated deficit	(79,365)	(62,013)	(43,975)	(25,563)	(17,048)
Total stockholders' equity (net capital deficiency)	(71,932)	(56,371)	(40,216)	(23,798)	(16,820)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 our consolidated financial statements and notes thereto.

Overview

We discover, develop and intend to commercialize innovative products to treat and prevent allergies, infectious diseases and chronic inflammatory diseases. 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 include AIC, an immunotherapy product candidate for treatment of ragweed allergy that has completed Phase II trials, our hepatitis B vaccine, which is nearing completion of two Phase II trials, and an inhaled therapeutic product candidate for treatment of asthma, which is currently in a pilot Phase II trial. Based on results from Phase II trials, we plan to initiate in 2004 Phase IIb and Phase III trials for AIC and Phase III trials for our hepatitis B vaccine. We intend to commercialize our hepatitis B vaccine only outside the U.S. In addition, we have a cancer therapeutic product in Phase I trials and preclinical programs targeting additional allergies using our ISS technology. We have other preclinical programs focused on chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies.

We have incurred significant losses since our inception. As of December 31, 2003, we had an accumulated deficit of approximately $79.4 million. We expect to incur substantial and increasing losses as we continue the development of those lead product candidates and preclinical and research programs that we have not partnered. If we were to receive regulatory approval for any of our product candidates not yet partnered, 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 commercial products that generate revenue. For the fiscal year ended December 31, 2003, our revenue was derived from government grants. Through the fiscal year ended December 31, 2002, we generated revenue primarily through research and development collaboration agreements.

Most of our expenditures to date have been for research and development activities and general and administrative expenses. 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, facility costs, supplies and depreciation of laboratory equipment. We anticipate that our research and development expense will increase in connection with expanded clinical trials, in particular in connection with our planned Phase IIb and III clinical trials for AIC and Phase III clinical trials for our hepatitis B vaccine, which we expect to initiate in 2004. Drug development is characterized by many uncertainties. These uncertainties include the time and resources required to successfully develop safe and effective product candidates, our ability to fund development of and establish collaborative relationships with third parties to commercialize our product candidates and the likelihood, timing and conditions of regulatory approval to commence various stages of clinical trials, and, ultimately, of approval to market our product candidates. Consequently, we are unable to estimate accurately the cost or time required to complete current and future clinical trials in any of our programs. We expense our research and development costs as they are incurred.

General and administrative expenses consist primarily of compensation and related benefits, facility costs and professional expenses, such as legal, accounting, consulting and public relations. We anticipate that general and administrative expenses will increase as a result of the expected expansion of our business, together with the additional costs associated with operating as a public company.

We have recorded no provision for Federal and state income taxes since inception. As of December 31, 2003, we had Federal net operating loss carryforwards of approximately $38.0 million. Utilization of net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. 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.

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 accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our consolidated financial statements and accompanying notes. On an on-going basis, we evaluate our estimates, including those related to terms of the research collaborations, investments, stock-based compensation, impairment issues, the estimated useful life of assets 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. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements, we believe that the following accounting policies relating to revenue recognition, clinical trial expenses and stock-based compensation expense are important to understanding and evaluating our reported financial results.

Revenue Recognition. We recognize revenue from collaboration agreements 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 or grant. Any amounts received in advance of performance are recorded as deferred revenue. Upfront payments are deferred and amortized over the estimated research and development period. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations or grants and milestones is nonrefundable. Payments from collaborators for the option to license technology or product rights in the future are deferred when received. When an option is exercised, revenue is recognized on a straight-line basis over the term of the resulting agreement. In the event that an option expires without exercise, the payment is recognized in full at the expiration of the agreement. Revenues related to government grants are recognized as the related research expenses are incurred. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Research and Development Expense. Research and development expenditures are charged to operations as incurred. Research and development expenses consist 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. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. 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 the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on the level of patient enrollment and activity according to the protocol. We monitor patient enrollment levels and related activity to the extent possible and adjust our estimates accordingly.

Stock-Based Compensation Expense. In connection with the grant of stock options to employees and non-employees, we record deferred stock compensation as a component of stockholders' equity (net capital deficiency). Deferred stock compensation for options granted to employees is the difference between the estimated fair value of our common stock on the date the options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. Deferred stock compensation for unvested options granted to non-employees is periodically re-measured, with any change in the estimated fair value from period to period recorded as a change in deferred stock compensation. Deferred stock compensation is amortized as a charge to operations over the vesting periods of the options using the straight-line method. We recorded stock-based compensation expense of approximately $1.8 million, $1.8 million, and $2.1 million for the years ended December 31, 2003, 2002, and 2001, respectively. As of December 31, 2003, we had $4.7 million of deferred stock-based compensation that will be amortized in future periods. 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.

Results of Operations

Years Ended December 31, 2003, and 2002

Collaboration and other revenue: Our revenue for the year ended December 31, 2003, was approximately $826,000, a decrease of 42.1% as compared to approximately $1.4 million in revenue for the year ended December 31, 2002. Revenue for the year ended December 31, 2003 resulted from grants by the National Institutes of Health. In the third quarter of 2003, the Company was awarded government grants totaling approximately $8.4 million to be received over three and one-half years to fund research and development of certain biodefense programs. The revenue will be recognized as the related expenses are incurred. Revenue for the year ended December 31, 2002 resulted from two research and development collaboration agreements and another agreement providing a customer an option to negotiate rights to license technology developed by us. The first of these two collaborations commenced in 1999 and focused on infectious diseases. This collaboration provided revenues of $990,000 for the year ended December 31, 2002, but did not generate any revenue for the year ended December 31, 2003. This collaboration was terminated by mutual consent in September 2002. The second of these two collaborations commenced in 2000 and focused on the treatment and prevention of hepatitis and HIV. This collaboration provided revenues of $188,000 for the year ended December 31, 2002 but did not generate any revenue for the year ended December 31, 2003. This collaboration was terminated by mutual consent in November 2002. The agreement providing a collaborator an option to negotiate rights to license technology developed by us commenced during 2002. This agreement generated revenue of $250,000 for the year ended December 31, 2002, but did not generate any revenue for the year ended December 31, 2003. This agreement lapsed in April 2002 when the collaborator did not exercise its option.

Research and development expenses: Research and development expenses were approximately $14.4 million for the year ended December 31, 2003, a decrease of 9.9% from approximately $16.0 million in research and development expenses 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, asthma and TZP 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.

General and administrative expenses: General and administrative expenses were approximately $4.2 million for the year ended December 31, 2003, an increase of 2.1% as compared to approximately $4.1 million in general and administrative expenses 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 key members 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 year ended December 31, 2003, and 2002, respectively.

Interest income, net: Interest income, net, was approximately $412,000 for the year ended December 31, 2003, a decrease of 33.7% as compared to approximately $621,000 in interest income, net, 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. The Company recorded a deemed dividend of $633,000 on the difference between the estimated fair value of the common stock at the issuance date and the conversion price of the ordinary shares.

Years Ended December 31, 2002, and 2001

Collaboration and other revenue: Our revenue for the year ended December 31, 2002, was approximately $1.4 million, a decrease of 39.5% as compared to approximately $2.4 million in revenue for the year ended December 31, 2001. Revenue for 2002 resulted from two research and development collaboration agreements and another agreement providing a customer an option to negotiate rights to license technology developed by us. The first of these two collaborations commenced in 1999 and focused on infectious diseases. This collaboration provided revenues of $990,000 during the year ended December 31, 2002, and $46,000 during the year ended December 31, 2001. This collaboration was terminated by mutual consent in September 2002. The second of these two collaborations commenced in 2000 and focused on the treatment and prevention of hepatitis and HIV. This collaboration provided revenues of $188,000 during the year ended December 31, 2002, and approximately $2.1 million during the year ended December 31, 2001. This collaboration was terminated by mutual consent in November 2002. The agreement providing a collaborator with an option to negotiate rights to license technology developed by us commenced during 2002. This agreement generated revenue of $250,000 during the year ended December 31, 2002 but did not generate any revenue during the year ended December 31, 2001. This agreement lapsed in April 2002 when the collaborator did not exercise its option.

Research and development expenses: Research and development expenses were approximately $16.0 million for the year ended December 31, 2002, a decrease of 8.1% as compared to research and development expenses of approximately $17.4 million for the year ended December 31, 2001. The decrease was due primarily to the decreased clinical trial costs associated with our Phase II trials for AIC. Non-cash stock-based compensation expense attributable to research and development expenses was approximately $953,000 and $1.0 million for the years ended December 31, 2002, and December 31, 2001, respectively.

General and administrative expenses: General and administrative expenses were approximately $4.1 million for the year ended December 31, 2002, a decrease of 9.0% as compared to approximately $4.5 million in general and administrative expenses for the year ended December 31, 2001, due primarily to lower headcount. Non-cash stock-based compensation expense included in general and administrative expense was approximately $0.9 million and $1.0 million for the years ended December 31, 2002, and 2001, respectively.

Interest income, net: Interest income, net, was approximately $621,000 for the year ended December 31, 2002, a decrease of 44.5% as compared to approximately $1.1 million in interest income, net for the year ended December 31, 2001. The decrease was primarily due to lower average cash balances coupled with lower average interest rate yields during 2002.

Recent Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board (the “FASB”) issued the FASB Interpretation No. 45 (“FIN 45”), Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, which clarifies the requirements for a guarantor’s accounting and disclosures of certain guarantees issued and outstanding. This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at its inception of guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of this interpretation are applicable on a prospective

basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements in this interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the Company's results of operations or financial position.

In November 2002, the EITF issued EITF Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). EITF 00-21 addresses how to account for arrangements that may involve delivery or performance of multiple products, services, and/or rights to use assets, and when and, if so, how an arrangement involving multiple deliverables should be divided into separate units of accounting. It does not change otherwise applicable revenue recognition criteria. It applies to arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The adoption of EITF 00-21 did not have a material impact on the Company's results of operations or financial position.

In January 2003, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 46, or FIN 46, "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in research and development or other activities on behalf of another company. However, the FASB deferred the effective date for variable interest entities created before February 1, 2003, to the period ending March 31, 2004, for calendar year-end companies. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. Our adoption of the disclosure requirements in January of 2003 did not have an impact on the Company's consolidated financial position and results of operations. The adoption of the recognition requirements of FIN 46 on January 1, 2004, is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity ("SFAS 150"). SFAS 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective the beginning of the first interim period after June 15, 2003. The adoption of SFAS 150 did not have a material impact on the Company's results of operations or financial position.

Liquidity and Capital Resources

We have financed our operations from inception primarily through sales of shares of convertible preferred stock and ordinary shares in a subsidiary, which have yielded a total of approximately $98.3 million in net cash proceeds and, to a lesser extent, through amounts received under collaborative agreements and government grants. As of December 31, 2003, we had approximately $29.1 million in cash, cash equivalents and marketable securities. Our funds are currently invested in highly liquid, investment-grade corporate and government obligations.

To the extent we raise additional capital by issuing equity securities, our stockholders would at that time experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product

candidates, or grant licenses on terms that are not favorable to us. Our future funding requirements will depend upon many factors, including, but not limited to:

- the progress and success of preclinical studies and clinical trials of our product candidates conducted by us or our collaborative partners or licensees;
- our ability to meet the milestones identified in our collaborative agreements that trigger payments;
- our ability to maintain and establish new corporate relationships and research collaborations;
- any changes in the breadth of our research and development programs;
- the costs and timing of regulatory approvals;
- competing technological and market developments;
- the costs and timing of obtaining, enforcing and defending our patent and intellectual rights;
- expenses associated with unforeseen litigation; and
- our ability to manage our growth.

Insufficient funds may require us 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.

Our operating activities used cash of approximately $14.4 million during the year ended December 31, 2003, compared to cash used in operating activities of approximately $14.0 million during the year ended December 31, 2002. This increase of approximately $0.4 million was due primarily to an increase in working capital, partially offset by a decrease in net loss. Our operating activities used cash of approximately $13.6 million during the year ended December 31, 2001. This increase of approximately $400,000 during the year ended December 31, 2002, over the prior year was due primarily to an increase in working capital, partially offset by a decrease in net loss.

Our investing activities provided cash of approximately $17.8 million during the year ended December 31, 2003, compared to cash used in investing activities of approximately $17.6 million during the year ended December 31, 2002. Cash provided by investing activities during the year ended December 31, 2003, consisted primarily of maturities and net sales of investments of approximately $18.0 million. Cash used in investing activities during the year ended December 31, 2002 consisted primarily of net purchases of investments of approximately $17.1 million. Our investing activities provided cash of approximately $14.5 million during the year ended December 31, 2001, consisting primarily of net sales and maturities of investments of approximately $15.6 million offset by an investment of approximately $1.1 million in property and equipment.

Our financing activities provided cash of approximately $14.9 million during the year ended December 31, 2003, compared to cash provided by financing activities of approximately $32.4 million during the year ended December 31, 2002. Cash provided by financing activities during the year ended December 31, 2003, consisted primarily of approximately $14.7 million in net proceeds from the issuance of ordinary shares in Dynavax Asia Pte. Ltd., our subsidiary based in Singapore. Dynavax Asia became a wholly owned subsidiary upon the closing of our initial public offering in February 2004. Cash provided by financing activities during the year ended December 31, 2002, consisted primarily of approximately $32.4 million in net proceeds from issuance of preferred stock. During the year ended December 31, 2001, cash used in financing activities was approximately $161,000 and consisted primarily of $152,000 in repayments on equipment financing.

In early February 2004 we entered into an agreement with UCB Farchim, S.A., a subsidiary of UCB, S.A., 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. UCB was also granted an option to license our peanut allergy program. According to terms of the agreement, we received an upfront payment of $8 million and may earn additional payments based on achieving defined clinical and regulatory milestones of up to $40 million. In addition, UCB is obligated to fund substantially all of the continued research and development of the licensed programs, as well as costs related to regulatory filings and potential product

launch, sales, and marketing. If any of the licensed product candidates is successfully developed and approved for sale, we will receive royalties on sales. We have retained an option to co-promote any approved product in the U.S. under specified circumstances. Both parties have the right to terminate the agreement in the future under specified circumstances.

We completed an initial public offering in February 2004, raising net proceeds of approximately $46.6 million from the sale of 6.9 million shares of common stock.

Long-term Debt and Operating Leases

We have no long-term debt, and as of December 31, 2003, we had contractual obligations related to operating leases as follows (in thousands):

	Payments Due by Period				
	Total	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Operating leases	$7,690	$710	$1,435	$1,474	$4,071

Our long-term commitments under operating leases shown above consist of payments relating to our real estate leases in Berkeley, California, expiring in May 2008 and March 2014, respectively, and our lease in Emeryville, California, expiring in March 2004.

We believe our existing cash, cash equivalents and marketable securities, together with the net proceeds of our initial public offering, will be sufficient to meet our anticipated cash requirements for at least the next 36 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. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators, government agencies and other licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may significantly harm our future capital position.

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, reduce the scope of, eliminate or divest one or more of our research, preclinical or clinical programs or discontinue our business.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. 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 be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized.

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 current investments, 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 the high quality and conservative nature of our longer-term investments, which are generally held to maturity, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk. All of our business is currently transacted in U.S. dollars. As a result, we have 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 Auditors

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, 2003 and 2002, 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, 2003. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dynavax Technologies Corporation at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

Palo Alto, California
January 31, 2004 except for Note 15 as to
which the date is February 24, 2004

Dynavax Technologies Corporation

Consolidated Balance Sheets

(in thousands, except per share amounts)

	December 31, 2003	2002
Assets		
Current assets:		
Cash and cash equivalents	$ 23,468	$ 5,171
Marketable securities	5,629	24,239
Grants receivable	220	—
Prepaid expenses and other current assets	1,422	717
Total current assets	30,739	30,127
Property and equipment, net	828	1,300
Other assets	18	51
Total assets	$ 31,585	$ 31,478
Liabilities, minority interest, convertible preferred stock, and stockholders' equity (net capital deficiency)		
Current liabilities:		
Accounts payable	$ 1,410	$ 1,396
Accrued liabilities	2,989	2,068
Deferred revenue	750	750
Total current liabilities	5,149	4,214
Commitments and contingencies		
Minority interest in Dynavax Asia	14,733	—
Convertible preferred stock: $0.001 par value; 61,767 and 40,732 shares authorized at December 31, 2003 and 2002, respectively; 39,514 shares issued and outstanding at December 31, 2003 and 2002 (liquidation value of $86,682 at December 31, 2003)	83,635	83,635
Stockholders' equity (net capital deficiency):		
Common stock: $0.001 par value; 28,333 and 17,667 shares authorized at December 31, 2003 and 2002, respectively; 1,884 and 1,849 shares issued and outstanding at December 31, 2003 and 2002, respectively	2	2
Additional paid-in capital	12,762	8,423
Deferred stock compensation	(4,677)	(2,120)
Notes receivable from stockholders	(654)	(714)
Accumulated other comprehensive income	—	51
Accumulated deficit	(79,365)	(62,013)
Total stockholders' equity (net capital deficiency)	(71,932)	(56,371)
Total liabilities, minority interest, convertible preferred stock, and stockholders' equity (net capital deficiency)	$ 31,585	$ 31,478

See accompanying notes.

Dynavax Technologies Corporation

Consolidated Statements of Operations

(in thousands, except per share amounts)

	Years Ended December 31,		
	2003	**2002**	**2001**
Revenues:			
Collaboration revenue	$ —	$ 1,427	$ 2,259
Grant revenue	826	—	100
Total revenues	826	1,427	2,359
Operating expenses:			
Research and development (including stock-based compensation expense of $1,284, $953 and $1,007 for the years ended December 31, 2003, 2002, and 2001, respectively)	14,381	15,965	17,363
General and administrative expenses (including stock-based compensation expense of $468, $868 and $1,049 for the years ended December 31, 2003, 2002, and 2001, respectively)	4,209	4,121	4,527
Total operating expenses	18,590	20,086	21,890
Loss from operations	(17,764)	(18,659)	(19,531)
Interest income, net	412	621	1,119
Net loss	(17,352)	(18,038)	(18,412)
Deemed dividend upon issuance of ordinary shares of Dynavax Asia	(633)	—	—
Net loss attributable to common stockholders	$(17,985)	$(18,038)	$(18,412)
Basic and diluted net loss per share attributable to common stockholders	$ (10.04)	$ (10.65)	$ (12.29)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	1,791	1,694	1,498
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (1.14)		
Shares used to compute pro form basic and diluted net loss per share attributable to common stockholders	15,839		

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					
	Shares	Amount	Shares	Par Amount	Additional Paid-In Capital	Deferred Stock Compensation	Notes Receivable From Stockholders	Accumulated Other Comprehensive Income
Balances at December 31, 2000	22,632	$51,285	1,871	$ 2	$10,353	$(7,938)	$(686)	$ 34
Series C convertible preferred stock issuance costs	—	(7)						
Issuance of common stock upon exercise of options at $3.00 to $12.00 per share for cash and notes receivable	—	—	35	—	78	—	(75)	—
Interest accrued on notes receivable from stockholders	—	—	—	—	—	—	(43)	—
Common stock repurchased	—	—	(4)	—	(5)	—	—	—
Deferred stock compensation	—	—	—	—	(615)	615	—	—
Amortization of deferred stock compensation	—	—	—	—	—	2,056	—	—
Comprehensive loss:								
Change in unrealized gain on marketable securities	—	—	—	—	—	—	—	(17)
Net loss			—	—	—	—	—	—
Comprehensive loss								
Balances at December 31, 2001	22,632	$51,278	1,902	$ 2	$ 9,811	$(5,267)	$(804)	$ 17
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	—	—	—
Interest accrued on notes receivable from stockholders	—	—	—	—	—	—	(46)	—

Repayment of notes receivable from stockholders	—	—	—	—	—	—	136	—
Common stock repurchased	—	—	(57)	—	(65)	—	—	—
Deferred stock compensation	—	—	—	—	(1,326)	1,326	—	—
Amortization of deferred stock compensation	—	—	—	—	—	1,821	—	—
Comprehensive loss:								
Change in unrealized gain on marketable securities	—	—	—	—	—	—	—	34
Net loss	—	—	—	—	—	—	—	—
Comprehensive loss								
Balances at December 31, 2002 (carried forward)	39,514	$83,635	1,849	$ 2	$ 8,423	$(2,120)	$(714)	$ 51

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Accumulated Deficit	Stockholders' Equity (Net Capital Deficiency)
Balances at December 31, 2000	$(25,563)	$(23,798)
Series C convertible preferred stock issuance costs		
Issuance of common stock upon exercise of options at $3.00 to $12.00 per share for cash and notes receivable	—	3
Interest accrued on notes receivable from stockholders	—	(43)
Common stock repurchased	—	(5)
Deferred stock compensation	—	—
Amortization of deferred stock compensation	—	2,056
Comprehensive loss:		
Change in unrealized gain on marketable securities	—	(17)
Net loss	(18,412)	(18,412)
Comprehensive loss		(18,429)
Balances at December 31, 2001	$(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	—	—
Issuance of common stock		

upon exercise of options at $0.30 to $12.00 per share for cash	—	3
Interest accrued on notes receivable from stockholders	—	(46)
Repayment of notes receivable from stockholders	—	136
Common stock repurchased	—	(65)
Deferred stock compensation	—	—
Amortization of deferred stock compensation	—	1,821
Comprehensive loss:		
Change in unrealized gain on marketable securities	—	34
Net loss	(18,038)	(18,038)
Comprehensive loss		(18,004)
Balances at December 31, 2002 (carried forward)	$(62,013)	$(56,371)

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

Net loss	—	—	—	—	—	—	—	—
Comprehensive loss								
Balances at December 31, 2003	39,514	$83,635	1,884	$ 2	$12,762	$(4,677)	$(654)	$ —

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Accumulated Deficit	Stockholders' Equity (Net Capital Deficiency)
Balances at December 31, 2002 (brought forward)	$(62,013)	$(56,371)
Issuance of common stock upon exercise of options at $0.50 to $3.00 per share for cash	—	73
Interest accrued on notes receivable from stockholders	—	(40)
Repayment of notes receivable from stockholders	—	100
Common stock repurchased	—	(43)
Deferred stock compensation, net of reversals	—	—
Amortization of deferred stock compensation	—	1,752
Deemed dividend upon issuance of ordinary shares of Dynavax	—	—
Asia	—	—
Comprehensive loss:		
Change in unrealized gain on marketable securities	—	(51)
Net loss	(17,352)	(17,352)
Comprehensive loss		(17,403)
Balances at December 31, 2003	$(79,365)	$(71,932)

See accompanying notes.

Dynavax Technologies Corporation

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2003	**2002**	**2001**
Operating activities			
Net loss	$(17,352)	$(18,038)	$(18,412)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	576	678	475
Loss on disposal of property and equipment	34	1	2
Accretion and amortization on marketable securities	581	329	161
Interest accrued on notes receivable from stockholders	(40)	(46)	(43)
Stock-based compensation expense	1,752	1,821	2,056
Changes in operating assets and liabilities:			
Accounts receivable	(220)	1,402	(902)
Prepaid expenses and other current assets	(705)	(323)	980
Other assets	33	3	(33)
Accounts payable	14	951	(403)
Accrued liabilities	921	(438)	1,464
Deferred revenue	—	(339)	1,043
Net cash used in operating activities	(14,406)	(13,999)	(13,612)
Investing activities			
Purchases of marketable securities	(7,022)	(28,754)	(8,507)
Maturities and sale of marketable securities	25,000	11,630	24,105
Purchases of property and equipment	(138)	(469)	(1,084)
Net cash provided by (used in) investing activities	17,840	(17,593)	14,514
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	(7)
Proceeds from issuance of common stock, net of issuance costs	73	3	3
Repurchase of common stock	(43)	(65)	(5)
Repayment of notes receivable from stockholders	100	136	—
Repayments of equipment financing	—	(15)	(152)
Net cash provided by (used in) financing activities	14,863	32,416	(161)
Net increase in cash and cash equivalents	18,297	824	741
Cash and cash equivalents at beginning of year	5,171	4,347	3,606
Cash and cash equivalents at end of year	$ 23,468	$ 5,171	$ 4,347

Dynavax Technologies Corporation

Statements of Cash Flows (continued)

(in thousands)

	Years Ended December 31,		
	2003	**2002**	**2001**
Supplemental disclosure of cash flow information			
Interest paid	$ —	$ —	$ 12
Supplemental disclosure of non-cash investing and financing activities			
Net unrealized gain (loss) on marketable securities	$ (51)	$ 34	$ 17
Issuance of common stock for notes receivable	$ —	$ —	$ 75
Repurchase of common stock for notes receivable	$ 43	$ 65	$ —
Interest accrued on notes receivable	$ 40	$ 46	$ 43
Deemed dividend upon issuance of ordinary shares of Dynavax Asia	$633	$ —	$ —

See accompanying notes.

Notes to Consolidated Financial Statements

1. The Company

Dynavax Technologies Corporation ("Dynavax" or the "Company") was incorporated on August 29, 1996, in California. The Company reincorporated on March 26, 2001, in Delaware. Dynavax is a biopharmaceutical company developing innovative products for treating and preventing allergies, infectious diseases and chronic inflammatory diseases.

In October 2003, the Company formed Dynavax Asia Pte. Ltd., or Dynavax Asia, a 100% owned Singapore subsidiary, which will focus on the Company's clinical and preclinical hepatitis B programs. Also 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 Company recorded the sale of the ordinary shares as a minority interest liability in the consolidated financial statements. The Company will support the development activities of Dynavax Asia through its U.S. personnel and through limited hiring in Singapore.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Dynavax and Dynavax Asia. 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 have been made to conform with the current year presentation.

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 functional currency of Dynavax Asia will be the Singapore dollar. Accordingly, the assets and liabilities of Dynavax Asia will be translated into U.S. dollars using the exchange rate in effect at the end of each period. Revenues and expenses will be translated using the average exchange rates for each period. Adjustments resulting from currency translations are included in comprehensive income (loss). Gains and losses resulting from currency transactions are recognized in current operations. However, planned operations in Singapore have not yet commenced. Consequently, to date all such funds flows have been denominated in U.S. dollars and virtually all operations of Dynavax Asia are conducted in the U.S. and, as such, no foreign currency transaction or translation gains or losses have been recorded as of December 31, 2003.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Fair Value of Financial Instruments

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

Marketable Securities

The Company classifies all marketable securities as available-for-sale in accordance with Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities* . Available-for-sale securities are carried at market value, with unrealized gains and losses included in accumulated other comprehensive income in stockholders' equity (net capital deficiency). Realized gains and losses are included in interest income. The cost of securities sold is based on the specific identification method. The Company's marketable securities consist primarily of corporate bonds that mature at various dates through 2004. No net unrealized gains (losses) or any other-than temporary losses were recognized at December 31, 2003.

	Fair Value at December 31,	
	2003	2002
Marketable securities, at cost	$5,629	$24,188
Unrealized gains	—	51
	$5,629	$24,239

Concentration of Credit Risk and Other Risks and Uncertainties

The Company's 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. The Company has not experienced any losses on its 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	
Significant Customers	Years ended December 31, 2003	2002	2001	Years ended December 31, 2003	2002
A	—	69%	2%	—	—
B	—	13%	88%	—	—
C	—	18%	—	—	—
D	100%	—	4%	100%	—

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 in countries where approval has been secured. 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 five years for laboratory equipment and furniture. 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 assets may be impaired. 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

The Company recognizes collaboration, upfront and other revenue based on the terms specified in the agreements, generally as work is performed or approximating the straight-line basis over the period of the collaboration. Any amounts received in advance of performance are recorded as deferred revenue. Revenue from milestones with substantive performance risk is recognized upon completion. All revenues recognized to date under these collaborations and milestones are nonrefundable.

Revenues related to government grants are recognized as the related research expenses are incurred. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Payments by collaborators for the option to license technology or product rights in the future are deferred when received. When an option is exercised, revenue is recognized on a straight-line basis over the term of the resulting license agreement. In the event that an option expires without exercise, the payment is recognized in full at the expiration of the agreement.

Research and Development Costs

Research and development costs are expensed as incurred and include costs associated with research performed pursuant to collaboration agreements. Research and development costs consist of direct and indirect internal costs related to specific projects, as well as fees paid to clinical research organizations, research institutions and other service providers, which conduct certain research activities on behalf of the Company. Expenses related to clinical trials are generally accrued based on the level of patient enrollment and activity according to the protocol. The Company monitors patient enrollment level and related activity to the extent possible and adjusts estimates accordingly.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. 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 be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized.

Stock-Based Compensation

The Company has adopted the pro forma disclosure requirements of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123") as amended by SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure* ("SFAS 148"). As permitted, the Company continues to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 ("APB 25") and its interpretations. Under APB 25, compensation expense is based on the difference, if any, on the date of grant, between the deemed fair value of the Company's common stock and the option exercise price, and is amortized over the respective vesting period of the options using the straight-line method. The pro forma effects of applying SFAS 123, as amended by SFAS 148, on the Company's net loss had compensation cost for options granted to employees been determined based on the fair value at grant date as prescribed by SFAS 123, would be as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2003	2002	2001
Net loss attributable to common stockholders:			
As reported	$(17,985)	$(18,038)	$(18,412)
Add:			
Stock-based employee compensation expense included in net loss	1,752	1,821	2,056
Less:			
Stock-based employee compensation expense determined under the fair value based method	(1,996)	(2,013)	(2,171)
Pro forma	$(18,229)	$(18,230)	$(18,527)
Net loss per share attributable to common stockholders:			
Basic and diluted, as reported	$ (10.04)	$ (10.65)	$ (12.29)
Basic and diluted, pro forma	$ (10.18)	$ (10.76)	$ (12.37)

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 estimate fair value of each option grant to employees is estimated on the date of grant using the Black-Scholes option pricing method with the following weighted average assumptions:

	Years ended December 31,		
	2003	2002	2001
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.4% to 2.9%	2.4% to 3.5%	4.3%
Expected life (in years)	4	4	4
Volatility	1.0	0.7	0.7

The weighted-average estimated fair value per share of employee stock options granted during 2003, 2002 and 2001 was $6.68, $1.32 and $1.95 respectively.

The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS 123, as amended by SFAS 148, and Emerging Issues Task Force ("EITF") No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). Deferred stock compensation for options granted to consultants is periodically remeasured as the underlying options vest in accordance with EITF 96-18. No stock options were issued to non-employees in either 2003 or 2002, while the Company recorded net reversals in compensation expense of $12,000 associated with stock options granted to non-employees in 2001.

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 income (loss). The Company includes unrealized holding gains and losses on marketable securities and foreign currency translation adjustments in accumulated other comprehensive income (loss).

Recent Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board (the "FASB") issued the FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, which clarifies the requirements for a guarantor's accounting and disclosures of certain guarantees issued and outstanding. This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain to recognize, at its inception of guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements in this interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the Company's consolidated results of operations and financial position.

In November of 2002, the Financial Accounting Standards Board issued Emerging Issues Task Force (referred to as EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF Issue No. 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF Issue No. 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF Issue No. 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting for an arrangement. The provisions of EITF Issue No. 00-21 applied to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company's adoption of the recognition requirements in July of 2003 of EITF Issue No. 00-21 did not have a material impact on it consolidated financial position or results of operations.

In January 2003, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 46, or FIN 46, "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in research and development or other activities on behalf of another company. However, the FASB deferred the effective date for variable interest entities created before February 1, 2003, to the period ending March 31, 2004, for calendar year-end companies. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. Our adoption of the disclosure requirements in January of 2003 did not have an impact on the Company's consolidated financial position and results of operations. The adoption of the recognition requirements of FIN 46 on January 1, 2004, is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity ("SFAS 150"). SFAS 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective the beginning of the first interim period after June 15, 2003. The adoption of SFAS 150 did not have a material impact on the Company's consolidated results of operations or financial position.

3. Dynavax Asia

In October 2003, the Company completed a sale of 15,200,000 ordinary shares in Dynavax Asia, which will be exchanged for 2,111,111 shares of common stock of the Company at a conversion price of $7.20 per share in connection with the closing of the Company's initial public offering. The Company's ownership in Dynavax Asia was reduced from 100% to 50% as a result of the sale of the ordinary shares to eight institutional investors. The sale raised net proceeds of $14.7 million. The Company recorded a deemed dividend of $633,000 on the difference between the estimated fair value of the common stock at the issuance date and the conversion price of the ordinary shares. The Company recorded the sale of the ordinary shares as a minority interest liability in the consolidated financial statements and will account for the 2004 conversion into common shares as a capital transaction.

4. Net Loss Per Share Attributable to Common Stockholders

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 attributable to common stockholders 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, stock subject to repurchase, 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.

The pro forma basic and diluted net loss per share attributable to common stockholders calculations assume the conversion of all outstanding shares of preferred stock into shares of common stock upon completion of the initial public offering using the as-if-converted method as of January 1, 2003 or the date of issuance, if later.

	Years Ended December,		
	2003	2002	2001
Historical (in thousands, except per share amounts)			
Numerator:			
Net loss attributable to common stockholders	$(17,985)	$(18,038)	$(18,412)
Denominator:			
Weighted-average common shares outstanding	1,849	1,886	1,889
Less: Weighted-average unvested common shares subject to repurchase	(58)	(192)	(391)
Denominator for basic and diluted net loss per share attributable to common stockholders	1,791	1,694	1,498
Basic and diluted net loss per share attributable to common stockholders	$ (10.04)	$ (10.65)	$ (12.29)
Pro forma net loss attributable to common stockholders	$(17,985)		
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (1.14)		
Shares used above:	1,791		
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock	14,048		
Shares used to compute pro forma basic and diluted net loss per share attributable to common stockholders	15,839		
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	7,548
Option to purchase common stock	1,334	691	279
Warrants	84	90	6
	17,241	14,393	7,833

5. Property and Equipment

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

	December 31,	
	2003	2002
Laboratory equipment	$ 1,937	$ 1,837
Computer and equipment	582	571
Furniture and fixtures	370	354
Leasehold improvements	298	321
	3,187	3,083
Less accumulated depreciation and amortization	(2,359)	(1,783)
	$ 828	$ 1,300

Depreciation and amortization expense on property and equipment was $576,000, $678,000 and $475,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2003	2002
Payroll and related expenses	$ 761	$ 712
Legal expenses	323	179
Third party scientific research expense	1,587	1,091
Other accrued liabilities	318	86
	$2,989	$2,068

7. Equipment Financing

In September 1997, the Company entered into a master financing agreement, which provides for borrowings for equipment purchased; amounts borrowed are collateralized by the related equipment. During 1998, the Company borrowed $55,000 and $107,000 under the master financing agreement. These notes were repaid in 48 monthly installments of $1,000 and $3,000, respectively. These notes bore interest at approximately 14% per annum and required a final payment equal to 5% of the original principal amounts, resulting in an effective interest rate of 15%. These notes were fully repaid as of December 31, 2002.

8. Commitments and Contingencies

Operating Lease

The Company leases its facilities under two non-cancelable operating leases that expire on March 31, 2004, and May 31, 2008. Rent expense for the years ended December 31, 2003, 2002 and 2001, was $631,000, $551,000 and $500,000 respectively.

Future minimum payments under the non-cancelable operating leases at December 31, 2003, are as follows (in thousands):

Year ending December 31,	
2004	$ 513
2005	454
2006	454
2007	454
2008	189
	$2,064

Guarantees and Indemnifications

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's 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, 2003.

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, 2003.

9. Stockholders' Equity (Net Capital Deficiency)

Convertible Preferred Stock

The Company has 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 (collectively referred to as "Preferred Stock") 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	Shares Issued and Outstanding at December 31, 2002
Series A	6,700	$1.00	6,700	6,700
Series B	9,033	$1.83	9,033	9,033
Series S-1	400	$5.00	400	400
Series R	430	$4.65	430	430
Series T	400	$5.00	400	400
Series C	5,669	$4.00	5,669	5,669
Series D	17,135	$2.06	16,882	16,882
Series E-1	22,000	$2.40	—	—
	61,767		39,514	39,514

From March 2002 to July 2002, the Company issued a total of 16,882,220 shares of Series D Preferred Stock for gross proceeds of $34,777,372. In connection with the issuance of the Series D Preferred Stock, the Company incurred issuance costs of $2,742,000, of which approximately $123,000 was settled by the issuance of 59,671 shares of Series D preferred Stock, and of which approximately $322,000 was settled by the issuance of a warrant to purchase 253,233 shares of Series D Preferred Stock.

Under contractual arrangements entered into by the Company and Dynavax Asia investors, the 15,200,000 ordinary shares of Dynavax Asia could be converted into 6,333,333 shares of Series E-1 Preferred Stock of the Company if certain conditions were met. Those conditions were not met at December 31, 2003.

Voting

The holders of Preferred Stock have various rights and preferences as follows:

Each share of Series A, Series B, Series C, Series D, Series E-1, Series S-1, Series R, and Series T 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, except as otherwise discussed below.

As long as any shares of Preferred Stock remain outstanding, with the exception of Series A Preferred Stock (in which case at least 500,000 shares of Series A Preferred Stock must remain outstanding), the Company must obtain a vote from the holders of at least 75%, 77%, and 66 2/3% of Series A, Series B, and Series C Preferred Stock, each voting as a separate class, respectively, in order to alter the certificate of incorporation or the bylaws, as they relate to that rights of such series of Preferred Stock, and changes in the authorized number of shares of, or designation, of Preferred Stock that results in additional securities that are on parity or senior to such series of Preferred Stock. Additionally, as long as any shares of Series D Preferred Stock remain outstanding, the Company must obtain a vote from holders of at least 51% of the Series D Preferred Stock voting as a single class in order to alter the Certificate of Incorporation, changes in the

authorized number of shares of, or designation, of Preferred Stock that results in additional securities that are on parity or senior to the Series D Preferred Stock, increase the size of the Board of Directors to a number of members in excess of nine, the payment of dividends or making other distributions of the Company's capital stock, certain mergers or consolidations of the Company, a sale of all or substantially all the assets of the Company, a liquidation or winding down of the Company and the Company's entering into strategic alliances involving the issuance of capital stock over $20,000,000. Additionally, as long as any shares of Series E-1 or E-2 Preferred Stock remain outstanding, the Company must obtain a vote from the deemed holders of at least 51% of Series E-1 Preferred Stock voting as a single class in order to alter the Certificate of Incorporation or Bylaws, changes in the authorized number of shares of, or designation, of Preferred Stock that results in additional securities that are on parity or senior to the Series E-1 Preferred Stock, increase the size of the Board of Directors the payment of dividends or making other distributions of the Company's capital stock, certain mergers or consolidations of the Company, a sale of all or substantially all the assets of the Company, a liquidation or winding down of the Company, any transaction between the Dynavax Asia and any officer, director or holder of 5% or more of the capital stock of the Company or Dynavax Asia, and certain additional issuance of Series E-1 Preferred 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 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 Preferred Stock.

The vote of a majority of the stockholders of Series A, Series B, Series C, and Series D Preferred Stock is required for certain issuances of common stock, any payment of dividend on, or redemption of, any shares of common stock or Preferred Stock, any agreement by the Company or its stockholders regarding certain mergers or consolidations of the Company and the sale of all or substantially all the assets of the Company, any increase or decrease the authorized number of shares of common stock or Preferred Stock, and any increase or decrease the size of the Board of Directors or to voluntarily dissolve or liquidate the Company. Holders of Series A, Series B, Series S-1, Series R, Series T, Series C, Series D, and Series E-1 Preferred Stock are entitled to receive non-cumulative dividends at the rate of 8% of the original issue price per annum, when and if declared by the Board of Directors. To date, the Company has not declared any dividends.

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 Preferred Stock own less than 51% of the resulting voting power of the surviving entity, the holders of the Series E-1 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 Preferred Stock, the holders of the Series D 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 Preferred Stock, the holders of all other 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 Preferred Stock, respectively) plus any accrued but unpaid dividends. After payment of the liquidation preference to holders of all series of 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 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 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 Preferred Stock is convertible into shares of the Company's common stock, at the option of the holder, according to a defined conversion ratio, which is subject to adjustment for dilution.

Each share of Series A, Series B, Series C, Series D, Series E-1, Series S-1, Series R, and Series T Preferred Stock automatically converts at an initial rate of one share of common stock for one share of Preferred Stock, adjusted for stock splits and certain other transactions, either i) at the affirmative election of the holders of at least 66 2/3% of the outstanding shares of 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 66 2/3%, 66 2/3%, 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. In addition, in the event of a sale of common stock, as defined per the amended and restated articles of incorporation, below the conversion price of Series A, Series B, Series C, Series D, Series E-1 and Series R Preferred Stock, such preferred stock conversion price shall be subject to adjustment. At December 31, 2003 and 2002, the outstanding shares of Series C Preferred Stock were convertible into an additional 492,100 and 400,492 shares of common stock, respectively and Series R Preferred Stock were convertible into an additional 48,741 and 40,246 shares of common stock, respectively, as a result of such adjustment. None of the shares convertible into shares of common stock had been converted as of those dates.

Redemption Rights

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

Reserved Shares

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2003	**2002**
Stock option plan	1,678,995	713,988
Conversion of preferred stock	15,823,239	13,612,026
Preferred stock warrant	84,411	84,411
	17,586,645	14,410,425

Warrant for Preferred Stock

In connection with the closing of the Series D Preferred Stock financing, in August 2002 the Company issued a warrant to purchase 253,233 shares of Series D Preferred Stock at an exercise price of $2.06 per share, to its placement agent. The estimated fair value of the warrant was valued using the Black-Scholes option-pricing model at approximately $322,000. This amount was recorded in convertible preferred stock as an issuance cost. The warrant is exercisable from the date of the grant for five years and remained outstanding at December 31, 2003.

Warrant for Common Stock

In connection with the master financing agreement, during 1997 the Company granted the lender a warrant to purchase 6,000 shares of common stock at an exercise price of $3.75 per share, subject to adjustments upon the occurrence of certain events such, as a merger of the Company, stock dividends and other distributions, and other antidilution events. The estimated fair value of the warrants was not significant. This warrant is exercisable from the date of the grant through the earlier of (i) six years after the date of

grant or (ii) the completion of an initial public offering of the Company's common stock with net proceeds of at least $10 million. At December 31, 2002, this warrant remained outstanding. The warrant was not exercised and expired as of December 31, 2003.

Stock Option Plan

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 officers and directors who are also considered as 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, officers, 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.

Activity under the 1997 Plan is set forth below:

		Options Outstanding	
	Shares Available for Grant	**Number of Shares**	**Weighted-Average Price Per Share**
Balance at December 31, 2000	188,839	169,145	$2.07
Options authorized	333,333	—	—
Options granted	(164,800)	164,800	$3.81
Options exercised	—	(35,121)	$2.22
Options canceled	19,880	(19,880)	$2.25
Shares repurchased	4,136	—	$1.05
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

The following summarizes options outstanding and exercisable under the 1997 Plan as of December 31, 2003:

Exercise Price	Number Outstanding	Average Remaining Contractual Life
		(In years)
$ 0.60	10,020	5.0
$ 1.20	20,972	6.2
$ 1.50	516,872	9.1
$ 3.00	774,802	9.1
$12.00	11,333	7.3
	1,333,999	9.0

The following summarizes options outstanding and exercisable under the 1997 Plan as of December 31, 2002:

Exercise Price	Number Outstanding	Average Remaining Contractual Life
		(In years)
$ 0.30	8,997	4.5
$ 0.60	10,618	6.0
$ 1.20	23,692	7.2
$ 1.50	250,533	9.7
$ 3.00	385,367	8.7
$12.00	12,000	8.3
	691,207	8.9

Deferred Stock Compensation

During the year ended December 31, 2003, the Company recorded deferred stock compensation for the excess of the estimated fair value of its common stock over the option exercise price at the date of grant of $4,517,775 related to options granted to employees. During the year ended December 31, 2003, the Company recorded reversals in deferred stock compensation resulting from employee terminations of $98,000. Stock-based compensation expense is being recognized over the option-vesting period of four years using the straight-line method.

During the year ended December 31, 2000, the Company recorded deferred stock compensation for the excess of the estimated fair value of its common stock over the option exercise price at the date of grant of $8,810,000 related to options granted to employees. During the years ended December 31, 2003 and 2002, the Company recorded reversals in deferred stock compensation resulting from employee terminations of $111,000 and $1,326,000, respectively. Stock-based compensation expense is being recognized over the option-vesting period of four years using the straight-line method.

For the years ended December 31,2003, 2002, and 2001, the Company recorded stock-based compensation expenses of $1,752,000, $1,821,000, and $2,056,000, respectively, in connection with options granted to employees.

For options granted to non-employees, the Company determined the estimated fair value of the options using the Black-Scholes option pricing model. Compensation expense is being recognized over the option-vesting period of four years. There was no compensation expense for the years ended December 31, 2003 and

2002. The Company recorded net reversals in compensation expense of $12,000 for the year ended December 31, 2001 in connection with options granted to non-employees.

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 $752,000 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 also collateralize these notes. At December 31, 2003, and 2002, $654,000 and $714,000, 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 principal investigator of the research project is Dr. Eyal Raz, a holder of 468,452 shares of the Company's common stock, and the university-nominated representative on the evaluation committee created to oversee aspects of this agreement is Dr. Dennis Carson, a holder of 468,452 shares of the Company's common stock and a member of the Company's Board of Directors.

The Company entered into agreements with holders of its preferred stock whereby it granted them registration rights with respect to their shares of common stock, including common stock issuable upon conversion of their preferred stock.

12. Collaborative Research, Development, and License Agreements

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, $20,000 and $20,000 and patent expenses of approximately $200,000, $405,000, and $278,000 in the years ended December 31, 2003, 2002, and 2001, respectively, in connection with these license agreements, each of which was recorded as research and development expense. Included in accounts payable at December 31, 2003, 2002 and 2001 was approximately $13,400, $66,000 and $78,000, respectively, related to patent expenses. The Company is obligated to make a one-time payment to UC upon the closing of the Company's initial public offering as partial consideration for the technology licenses. A charge to operations will be recorded in the period the payment becomes probable, which is expected to be upon the closing of the Company's initial public offering.

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." Title to any inventions shall be determined in accordance with U.S. Patent laws. The project commenced in January 1999 and will continue for a period of five years, unless terminated in accordance with the terms of the agreement. The Company agreed to fund and support future project costs of approximately $1 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 approximately $711,000, $1,026,000 and $986,000 during the years ended December 31, 2003, 2002 and 2001, respectively. The principal investigator of the research project is one of the Company's founders and stockholders.

Other Collaborative Agreements

In November 1999, the Company entered into a collaboration agreement with Stallergènes to develop and commercialize products to treat seasonal allergies. Under this agreement, both the Company and Stallergènes agreed to conduct preclinical and clinical development activities on two different forms of treatment for a particular allergy. Additionally, the Company granted Stallergènes a nonexclusive option, which has expired, to negotiate a license agreement. During 2001, revenues of $150,000 have been recognized. Separately, Stallergènes purchased 400,000 shares of Series S-1 Preferred Stock at $5.00 per share on November 22, 1999. The agreement lapsed in April 2002.

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 $1,500,000 for the first product and an additional $600,000 for the second product being developed. Additionally, the Company granted Aventis a nonexclusive option, which has expired, to negotiate a license agreement. The Company received an up-front payment of $1,100,000, all of which has been earned and recognized as revenue through December 31, 2001. During 2002, a further $990,000 of revenue was recognized for completed collaboration work. The agreement was mutually terminated on September 2002. Separately, Aventis purchased 215,054 shares of Series R Preferred Stock at $4.65 per share on March 7, 2000.

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 $250,000 based on achievement of a milestone. During 2002, the Company recognized revenue of $188,000 in relation to the collaboration and license agreement. The agreement was mutually terminated on November 25, 2002. Separately, Triangle Pharmaceuticals purchased 400,000 shares of Series T Preferred Stock at $5.00 per share on March 31, 2000.

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 certain milestones outlined in the agreement. Additionally, the Company will make various payments to BioSeek based on the success and timing of the Company's signing of a third party partnering agreement where the Company grants to the third party, directly or indirectly, any right or option to market, sell, distribute or otherwise commercialize a thiazolopyrimidine (TZP) product in any geographic territory. The agreement may be terminated by either party prior to BioSeek meeting the first contractual milestone, in accordance with the terms of the agreement. As of December 31, 2003, no payments had been made to BioSeek as no milestones had been achieved.

In the third quarter of 2003, the Company was awarded government grants totaling approximately $8,400,000 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. The revenue will be recognized as the related expenses are incurred. For the year ended December 31, 2003, $706,000 was recognized as revenue.

License and Supply Agreement

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 without charge 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 $519,000 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.

13. Income Taxes

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

	December 31, 2003	2002
Deferred tax assets:		
Net operating loss carry forwards	$ 14,385	$ 10,227
Research tax credit carry forwards	1,436	1,122
Accruals and reserves	1,315	85
Depreciation and amortization	12,365	11,529
Other	187	177
Total deferred tax assets	29,688	23,140
Less valuation allowance	(29,688)	(23,140)
	$ —	$ —

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, 2003 and 2002. The valuation allowance increased $6,548,000 and $4,251,000 during the years ended December 31, 2003 and 2002, respectively.

As of December 31, 2003, the Company had federal net operating loss carryforwards of approximately $38,000,000, which expire at various dates from 2011 through 2023, and federal research and development tax credits of approximately $900,000, which expire at various dates from 2018 through 2023 if not utilized.

As of December 31, 2003, the Company had California state net operating loss carryforwards of approximately $24,000,000, which expire at various dates from 2006 through 2013, and California state research and development tax credits of approximately $600,000, which do not expire.

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

15. Subsequent Events

Reverse Stock Split

In October 2003, the Board of Directors and Stockholders approved a one-for three reverse stock split of its outstanding shares of common stock. An amended and restated certificate of incorporation reflecting the

reverse stock split was filed on February 3, 2004. All common share and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this stock split.

License and Development Agreement with UCB

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 million upfront payment and may earn up to $40 million in milestone payments based on achieving defined clinical and regulatory objectives. In addition, UCB agreed to fund continued research and development of the licensed programs, as well as costs relating to regulatory filings and potential launch, sales and marketing. If any of the licensed product candidates are successfully developed and approved for sale, the Company will receive royalties on sales. The Company has retained an option to co-promote any approved product in the United States, in which case the Company would recognize revenue from sales in lieu of receiving royalty payments. The agreement remains in effect until the later of expiration of patent coverage of licensed products or 2018, unless terminated sooner according to its terms.

Facilities

In January 2004, the Company entered into a 10-year lease for approximately 20,500 square feet of laboratory and office space in Berkeley, California expiring in March 2014 to replace its Emeryville lease and provide for additional space.

In January 2004, the Company amended its operating lease for one of its facilities to include an option to terminate its liability prior to the expiration of the original lease term. Under the terms of the amendment, the Company will pay a termination fee if it chooses to exercise the termination option.

2004 Stock Incentive Plan

In January 2004, the Board of Directors and Stockholders adopted the 2004 Stock Incentive Plan under which 3,500,000 shares have 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 2004 Stock Incentive Plan became effective on February 11, 2004.

The exercise price of all incentive stock options granted under the Company's 2004 Stock Incentive 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.

2004 Non-employee Director Option Program

In January 2004, the Board of Directors and Stockholders adopted the 2004 Non-employee Director Option Program as part of the Company's 2004 Stock Incentive Plan. The 2004 Non-employee Director Option Program is a discretionary program under the 2004 Stock Incentive Plan and is not subject to stockholder approval. The 2004 Non-employee Director Option Program became effective on February 11, 2004.

2004 Employee Stock Purchase Plan

In January 2004, the Board of Directors and Stockholders adopted the 2004 Employee Stock Purchase Plan under which 250,000 shares have 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 2004 Employee Stock Purchase Plan is intended to qualify as an "Employee Stock Purchase Plan" under Section 423 of the Internal Revenue Code and became effective on February 11, 2004.

The price per share at which shares of common stock are to be purchased under the Company's 2004 Employee Stock Purchase Plan during any purchase period is the lesser of 85% of the fair market value of the common stock on the date of the grant of the option, which is the commencement of the offer period; or 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period.

Certificate of Incorporation

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 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.

Initial Public Offering

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 $46,586,000. As a result of the initial public offering, all outstanding shares of Preferred Stock converted to 13,712,128 shares of common stock and the 15,200,000 shares of ordinary stock in Dynavax Asia converted into 2,111,111 shares of common stock, making Dynavax Asia a wholly-owned subsidiary as of that date.

16. Selected Quarterly Financial data (unaudited, in thousands, except per share amounts)

	Year Ended December 31, 2003				Year Ended December 31, 2002			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	$ —	$ 96	$ 23	$ 707	$ 918	$ 250	$ 188	$ 71
Net loss attributable to common stockholders	$(4,718)	$(3,955)	$(4,139)	$(5,173)	$(3,647)	$(4,439)	$(5,239)	$(4,713)
Basic and diluted net loss per share attributable to common stockholders	$ (2.68)	$ (2.23)	$ (2.30)	$ (2.83)	$ (2.23)	$ (2.64)	$ (3.06)	$ (2.70)
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	1,759	1,776	1,803	1,827	1,638	1,679	1,712	1,746

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

Not applicable.

ITEM 9A. 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 December 31, 2003. Based on that evaluation, the CEO and CFO concluded that the Company's disclosure controls and procedures were effective as of such date to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There were no changes in the Company's internal control over financial reporting that 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.

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 2004 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, 2003.

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) The following documents are filed as part of this report on Form 10-K:

1. Financial Statements:

2. Financial Statement Schedules: None, as all required disclosures have been made in the consolidated financial statements and notes thereto.

3. 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*	2003 Stock Incentive Plan
10.4*	2003 Employee Stock Purchase Plan
10.5*	Triple Net Laboratory Lease, dated as of January 30, 1998, between Dynavax Technologies Corporation and Fifth & Potter Street Associates, LLC, including an amendment thereof
10.6*	Standard Industrial/ Commercial Multi-Tenant Lease — Gross, dated January 31, 2001, between Dynavax Technologies Corporation and Neil Goldberg and Hagit Cohen
10.7*†	Development Collaboration Agreement, dated June 10, 2003, between Dynavax Technologies Corporation and BioSeek, Inc.
10.8*†	License and Supply Agreement, dated October 28, 2003, between Dynavax Technologies Corporation and Berna Biotech AG
10.9*†	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.
10.10*†	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.
10.11*	Management Continuity Agreement, dated as of October 15, 2003, between Dynavax Technologies Corporation and Dino Dina
10.12*	Management Continuity Agreement, dated as of September 2, 2003, between Dynavax Technologies Corporation and Daniel Levitt
10.13*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and William J. Dawson
10.14*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Stephen Tuck
10.15*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Robert Lee Coffman
10.16*	Management Continuity and Severance Agreement, dated as of August 1, 2003, between Dynavax Technologies Corporation and Gary Van Nest
10.17*	Lease, dated as of January 7, 2004, between Dynavax Technologies Corporation and 2929 Seventh Street, L.L.C.
10.18*	License and Development Agreement, dated February 5, 2004, between Dynavax Technologies Corporation and UCB Farchim, SA
21.1**	Subsidiaries of Dynavax Technologies Corporation
23.1**	Consent of Ernst & Young LLP, Independent Auditors
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 902 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to Section 902 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

** 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

(b) There were no reports on Form 8-K filed in the fourth quarter of 2003.

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, on March 29, 2004.

DYNAVAX TECHNOLOGIES CORPORATION

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

Dino Dina, M.D.
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes Dino Dina, M.D. and William J. Dawson 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 Dino Dina	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 29, 2004
/s/ WILLIAM J. DAWSON William J. Dawson	Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 29, 2004
/s/ DANIEL S. JANNEY Daniel S. Janney	Chairman of the Board	March 29, 2004
/s/ LOUIS C. BOCK Louis C. Bock	Director	March 29, 2004
/s/ DENNIS CARSON, M.D. Dennis Carson, M.D.	Director	March 29, 2004
/s/ JAN LESCHLY Jan Leschly	Director	March 29, 2004
/s/ ARNOLD ORONSKY, PH.D. Arnold Oronsky, Ph.D.	Director	March 29, 2004
/s/ DENISE M. GILBERT Denise M. Gilbert, Ph.D.	Director	March 29, 2004

Exhibit 21.1

List of Subsidiaries

Dynavax Asia Pte. Ltd.

Exhibit 31.1

CERTIFICATIONS

I, Dino Dina, certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation;

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)) 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) 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

   c) 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.

Date: March 29, 2004

By: /s/ DINO DINA

Dino Dina, M.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, William J. Dawson, certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation;

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)) 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) 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

c) 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.

Date: March 29, 2004

By: /s/ WILLIAM J. DAWSON

William J. Dawson
Chief Financial Officer

Exhibit 32.1

Dynavax Technologies Corporation
Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

I, Dino Dina, the Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), certify that to the best of my knowledge:

(i) the Annual Report of the Company on Form 10-K dated March 29, 2004 for the fiscal year ended December 31, 2003, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the said Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2004

By: /s/ DINO DINA

Dino Dina, M.D.
President and Chief Executive Officer

Exhibit 32.2

Dynavax Technologies Corporation
Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

I, William J. Dawson, the Chief Financial Officer of Dynavax Technologies Corporation (the "Company"), certify that to the best of my knowledge:

(i) the Annual Report of the Company on Form 10-K dated March 29, 2004 for the fiscal year ended December 31, 2003, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the said Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2004

By: /s/ WILLIAM J. DAWSON

William J. Dawson
Chief Financial Officer