

DYNAVAX TECHNOLOGIES CORP

Form 10-K

March 17, 2008

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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, 2007
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 000-50577

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

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

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

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

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

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

Title of Each Class:

Name of Each Exchange on Which Registered:

None

None

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2007 as reported on the Nasdaq Global Market, was approximately \$161,011,098. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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FORWARD-LOOKING STATEMENTS

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

Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this document. No assurance can be given that the risk factors described in this Annual Report on Form 10-K are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.

This Annual Report on Form 10-K includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners.

PART I

ITEM 1. BUSINESS

Overview

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

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

Recent Developments

HEPLISAV

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

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

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

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

Allergy Franchise

TOLAMBA

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

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

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

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Peanut and Cat Allergy Therapies

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

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

Influenza Vaccine

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

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

The Immune System

The immune system is the body's natural defense mechanism against infectious pathogens, such as bacteria, viruses and parasites, and plays an important role in identifying and eliminating abnormal cells, such as cancer cells. The body's first line of defense against any foreign substance is a specialized function called innate immunity, which serves as a rapid response that protects the body during the days or weeks needed for a second longer-term immune response, termed adaptive immunity, to develop. Unique cells called dendritic cells have two key functions in the innate immune response. They produce molecules called cytokines that contribute to the killing of viruses and bacteria. In addition, they ensure that pathogens and other foreign substances are made highly visible to specialized helper T cells, called Th1 and Th2 cells, which coordinate the longer-term adaptive immune response. Dendritic cells recognize different types of pathogens or offending substances and are able to guide the immune system to make the most appropriate type of response. When viruses, bacteria and abnormal cells such as cancer cells are encountered, dendritic cells trigger a Th1 response, whereas detection of a parasite infection leads dendritic cells to initiate a Th2 response. Th1 and Th2 responses last for extended periods of time in the form of Th1 and Th2 memory cells, conferring long-term immunity.

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

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

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

ISS and the Immune System

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

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We believe ISS have the following benefits:

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

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

ISS, in conjunction with an allergen or antigen, establish populations of memory Th1 cells, allowing the immune system to respond appropriately to each future encounter with a specific pathogen or allergen, leading to long-lasting therapeutic effects.

We have developed a number of proprietary ISS compositions and formulations that make use of the different ways in which the innate immune system responds to ISS. Depending on the indication for which ISS is being explored as a therapy, we use ISS in different ways.

ISS Linked to Allergens

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

ISS Linked to or Combined with Antigens

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

ISS Alone

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

Advanced ISS Technologies

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

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

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

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

Our Primary Development Programs

Our primary development programs are HEPLISAV, Allergy and Influenza.

HEPLISAV: Our Hepatitis B Vaccine Candidate

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

Clinical Status

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

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

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

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

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

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Commercial Opportunity

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

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

Allergy Franchise

TOLAMBA for Ragweed Allergy

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

Clinical Status

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

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

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

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

Commercial Opportunity

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

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

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

Peanut and Cat Allergy Therapies

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

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

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

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Preclinical Status

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

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

Commercial Opportunity

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

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

Influenza Vaccine

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

Preclinical Status

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

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

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

Commercial Opportunity

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

Additional Programs

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

Cancer Therapy

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

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

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

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP and certain of its affiliates (Symphony) to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development (Development Programs). The agreements provided for the formation of Symphony Dynamo, Inc. (SDI). Pursuant to the agreements, Symphony invested \$50.0 million in SDI to fund the Development Programs, and we licensed to SDI our intellectual property rights related to the Development Programs.

Hepatitis B Therapy

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

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

Asthma

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

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration.

Autoimmune Disorders

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

Intellectual Property

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

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

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

own for selected indications.

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

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

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies including Pfizer, Inc., or Pfizer, as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned or licensed to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use or sell any products. The existence of third-party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. We have developed second-generation technology that we believe reduces many of these risks.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. U.S. Patent Office interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. Pfizer has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of ISS in the United States. We may not prevail in any of these actions or proceedings and an adverse outcome in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties, or require us to cease using some of our technology.

Our policy is to require each of our employees, consultants and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. These agreements also generally provide that we own all inventions conceived by the individuals in the course of rendering their employment or services to us.

Manufacturing

We rely on a number of third parties and our facility in Düsseldorf, Germany for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the combination of the antigens and ISS, and the fill and finish.

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

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

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

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

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

Marketing

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

Competition

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

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

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

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

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

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

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

Our ISS asthma product candidate would indirectly compete with existing asthma therapies, including corticosteroids, leukotriene inhibitors and IgE monoclonal antibodies, including those produced by Novartis, AstraZeneca, Schering-Plough Corporation and GSK. We consider these existing therapies to be indirect competition because they only attempt to address the symptoms of the disease and, unlike our product candidate, do not attempt to address the underlying cause of the disease. We are also aware of a preclinical inhaled product, which may target the underlying cause of asthma, rather than just the symptoms, which is being developed by Sanofi-Aventis under a collaboration agreement with Pfizer. This product, if approved and commercialized, may compete directly with our asthma product candidate.

Many of the entities developing and marketing these competing products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than us. Smaller or early-stage companies may also prove to be significant competitors, particularly for collaborative agreements with large, established companies and access to capital. These entities may also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs.

Regulatory Considerations

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

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

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

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

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

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

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

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

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Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval or clearance. Further, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. The approval process takes many years, requires the expenditures of substantial resources, involves post-marketing surveillance and may involve requirements for additional post-marketing studies. The FDA may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. The FDA may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing. Delays experienced during the governmental approval process may materially reduce the period during which we will have exclusive rights to exploit patented products or technologies. Delays can occur at any stage of drug development and as result of many factors, certain of which are not under our control, including but not limited to the following:

lack of efficacy, or incomplete or inconclusive results from clinical trials;

unforeseen safety issues;

failure by investigators to adhere to protocol requirements, including patient enrollment criteria;

slower than expected rate of patient recruitment;

failure by subjects to comply with trial protocol requirements;

inability to follow patients adequately after treatment;

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

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

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

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

The stages of the FDA regulatory process include research and preclinical studies and clinical trials in three sequential phases that may overlap. Research and preclinical studies do not involve the introduction of a product candidate in human subjects. These activities involve identification of potential product candidates, modification of promising

candidates to optimize their biological activity, as well as preclinical studies to assess safety and effectiveness in animals. In clinical trials, the product candidate is administered to humans. Phase 1 clinical trials typically involve the administration of a product candidate into a small group of healthy human subjects. These trials are the first attempt to evaluate a drug's safety, determine a safe dose range and identify side effects. During Phase 2 trials, the product candidate is introduced into patients who suffer from the medical condition that the product candidate is intended to treat. Phase 2 studies are designed to evaluate whether a product candidate shows evidence of effectiveness, to further evaluate dosage, and to identify

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possible adverse effects and safety risks. When Phase 2 evaluations demonstrate that a product candidate appears to be both safe and effective, Phase 3 trials are undertaken to confirm a product candidate's effectiveness and to test for safety in an expanded patient population. If the results of Phase 3 trials appear to confirm effectiveness and safety, the data gathered in all phases of clinical trials form the basis for an application for FDA regulatory approval of the product candidate.

We and all of our contract manufacturers are required to comply with the applicable FDA current good manufacturing practice (GMP) regulations. Manufacturers of biologics also must comply with FDA's general biological product standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Good manufacturing practice regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation. Prior to granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet good manufacturing practice requirements before we can use them in the commercial manufacture of our products. In addition, our facilities are subject to periodic inspections by the FDA for continued compliance with good manufacturing practice requirements during clinical development as well as following product approval. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal.

Outside the U.S., our ability to market a product is contingent upon receiving marketing authorization and pricing or reimbursement approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country.

At present, foreign marketing authorizations may be applied for at a national level, although within the European Union registration procedures are mandatory for biotechnology and some other drugs and are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

Employees

As of December 31, 2007, we had 173 full-time employees, including 26 Ph.D.s, 3 M.D.s and 23 others with advanced degrees. Of the 173 employees, 131 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement, and we believe our relations with our employees are good.

Available Information and Website Address

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

ITEM 1A. RISK FACTORS.

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

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and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$227.9 million as of December 31, 2007. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors and are scheduled to terminate in 2009. We anticipate that we will incur substantial additional net losses for the foreseeable future as a result of our investment in research and development activities.

We do not have any products that generate significant revenue. Clinical trials for certain of our product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

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

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations or raise additional capital on less favorable terms.

If we are unable to secure additional funding, we will have to reduce or discontinue operations.

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding may not allow us to continue operations as currently planned. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations, and any change in plans may increase these outlays and expenditures. We may be unable to obtain additional capital on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations.

The success of our TLR9 product candidates depends on achieving successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our TLR9 product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced TLR9 product candidates. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with

our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. For example, we recently announced a clinical hold by the FDA on two Investigational New Drug (IND) applications for HEPLISAV due to a serious adverse event (SAE) in a Phase 3 study. Pending further investigation and resolution satisfactory to the FDA and foreign regulatory authorities, there can be no assurance that HEPLISAV can be further developed, or even

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

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

Our clinical trials may be extended, suspended, delayed or terminated at any time. Even short delays in the commencement and progress of our trials may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects or inadequate supply of the product candidate. In addition, our ability to conduct clinical trials for some of our product candidates is limited due to the seasonal nature. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the target population is available for testing, which could result in a delay of an entire year.

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA. Any extension, suspension, termination or unanticipated delays of our clinical trials could:

adversely affect our ability to timely and successfully commercialize or market these product candidates;

result in significant additional costs;

potentially diminish any competitive advantages for those products;

adversely affect our ability to enter into collaborations, receive milestone payments or royalties from potential collaborators;

cause us to abandon the development of the affected product candidate; or

limit our ability to obtain additional financing on acceptable terms, if at all.

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

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, we or our contract manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and will be subject to periodic inspection by the FDA

and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also

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result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

Our most advanced product candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.

Our most advanced product candidates in clinical trials are based on our 1018 ISS compound, and substantially all of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay or discontinue all of our clinical trials. In addition, as all of our clinical product candidates contain ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials and for fulfilling our manufacturing obligations under our collaboration with Merck. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates or breach of our obligations under our Merck collaboration.

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

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

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

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

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

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

We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our clinical trials would delay our ability to commercialize our products and could have a material adverse effect on our business and operations.

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

Even if we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community. The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to successfully market any approved product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

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

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

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

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Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to treat or prevent infectious diseases, allergy, asthma and cancer, as well as those focusing more generally on the immune system. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. If we are unable to compete successfully, we may not be able to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop and commercialize our product candidates and achieve our objectives.

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

We may develop, seek regulatory approval for and market our product candidates outside the United States, requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may introduce certain of our product candidates in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States could impose substantial burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;

- compliance with varying international regulatory requirements, laws and treaties;

- securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

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

adverse tax consequences;

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the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
regional and geopolitical risks.

If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

We rely on our licenses from the Regents of the University of California. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend upon our license arrangements with the Regents of the University of California, or UC. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate our agreements or convert exclusive to non-exclusive licenses. In addition, our license agreements with UC may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. We are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV or any similar product candidate in the United States, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. In addition, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

One of our potential competitors, Pfizer, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, that may be asserted against our ISS products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own

proprietary technologies in order to commercialize one or more of our formulations of ISS in the U.S. other than with respect to HEPLISAV. Such a license may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

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

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

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

The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the United States, where we may only be able to obtain limited patent protection.

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

- we might not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary

rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

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

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

In July 2007, we entered into a funding arrangement with Deerfield management, or Deerfield, to support our further development of our allergy product programs, including TOLAMBA. Our continued access to the funding is dependent upon our successful achievement of specified milestones in a timely manner. There can be no assurance that TOLAMBA will be entered into planned clinical studies or successfully achieve the planned end points, and failure to successfully further develop TOLAMBA according to our current clinical plans may result in the termination of further development efforts. Moreover, even if we achieve the planned clinical results, we will be required to issue additional warrants to purchase up to 2,000,000 shares of our Common Stock and repay outstanding loans to the Deerfield. We may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to repay the loan at maturity. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.

We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some or all of the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise our option prior to the expiration of the development period, and even if we decide to exercise, we may not have the financial resources to exercise our option in a timely manner.

In April 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapeutics (Development Programs) to Symphony Dynamo, Inc. (SDI) in consideration for a commitment from Symphony Capital Partners, LP and certain of its affiliates (Symphony) to provide \$50.0 million of capital to advance the Development Programs. As part of the arrangement, we received an exclusive purchase option (Purchase Option) to acquire all of the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices ranging from \$74.7 to \$144.1 million. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15.0 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The intellectual property rights to the remaining cancer and hepatitis C therapy programs not purchased through the exercise of the Purchase Option will remain with SDI.

We and SDI jointly manage the Development Programs and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our Purchase Option. If we do not exercise the Purchase Option prior to its expiration, then our rights in and with respect to the Development Programs will terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement.

If we elect to exercise the Purchase Option, we will be required to make a substantial payment of at least \$74.7 million, increasing thereafter quarterly, which at our discretion may be paid partially in shares of our common stock. As a result, in order to exercise the Purchase Option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the Purchase Option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the Purchase Option, even if we paid

a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.

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We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

We face uncertainty related to coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

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

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

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

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

progress or results of any of our clinical trials or regulatory efforts, in particular any announcements regarding the progress or results of our planned trials;

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

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our ability to raise additional capital to fund our operations;

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

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

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

our ability to enter into and maintain collaborations;

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

changes in government regulations, general economic conditions, industry announcements;

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

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

volume of trading in our common stock

One or more of these factors could cause a decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

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

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

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

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

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

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

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

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

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

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent auditors are unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 67,000 square feet of laboratory and office space in Berkeley, California (the Berkeley Lease) under agreements expiring in September 2014, of which approximately 3,000 square feet is subleased through August 2010. The Berkeley Lease can be terminated at no cost to us in September 2009 but otherwise extends automatically until September 2014. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany (the Düsseldorf Lease) under lease agreements expiring in March 2023.

ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

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

Our common stock is traded on the Nasdaq Global Market under the symbol DVAX. Public trading of our common stock commenced on February 19, 2004. The following table sets forth for the periods indicated the high and low sale prices per share of our common stock on the Nasdaq Global Market.

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

As of February 29, 2008, there were approximately 104 holders of record of our common stock, as shown on the records of our transfer agent. The number of record holders does not include shares held in street name through brokers.

Dividends

We do not pay any cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Use of Proceeds from Sales of Registered Securities

On December 27, 2007, pursuant to agreements with Deerfield we issued to Deerfield Management and their affiliates warrants to purchase 1,000,000 shares of our common stock at a price of \$5.65 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.71 per share. We filed a registration statement on Form S-3 (File No. 333-149117) on February 8, 2008 with the Securities and Exchange Commission with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates. We anticipate filing the related prospectus supplement by April 2008.

On October 18, 2007, pursuant to agreements with Deerfield we issued to Deerfield Management and their affiliates warrants to purchase 1,300,000 shares of our common stock at a price of \$5.75 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.79 per share. We filed a registration statement on Form S-3 (File No. 333-147455) on November 16, 2007, as amended on November 30, 2007 with the Securities and Exchange Commission and the related prospectus supplement dated December 5, 2007 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates.

On July 18, 2007, pursuant to agreements with Deerfield we issued to Deerfield Management and their affiliates warrants to purchase 1,250,000 shares of our common stock at a price of \$5.13 per share, representing a 20% premium over the applicable 15-day trading range average of \$4.36 per share. We filed a registration statement on Form S-3 (File No. 333-145836) on August 31, 2007 with the Securities and

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Exchange Commission and the related prospectus supplement dated September 14, 2007 with respect to the shares subject to purchase upon exercise of the warrants issued to Deerfield Management and their affiliates.

On December 6, 2006, pursuant to agreements with Azimuth Opportunity Ltd., we issued 1,663,456 shares at a weighted average price of \$9.02 per share and realized aggregate proceeds of \$15.0 million. The shares were issued pursuant to the Registration Statement on Form S-3 (File No. 333-127930) filed on August 29, 2005 with the Securities and Exchange Commission and the related prospectus supplement dated December 6, 2006.

On October 10, 2006, we completed an underwritten public offering of 7,130,000 shares of common stock, including 930,000 shares subject to the underwriters' over-allotment option at a public offering price of \$4.40 per share and realized aggregate proceeds of \$31.4 million. The offering was made pursuant to the Registration Statement on Form S-3 (File No. 333-137608) filed on September 27, 2006 with the Securities and Exchange Commission and the related prospectus supplement dated October 4, 2006.

On April 18, 2006, pursuant to agreements with Symphony Capital Partners, LP, we issued to Symphony Dynamo Holdings LLC a five-year warrant to purchase 2,000,000 shares of our common stock at a price of \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. We filed a registration statement on Form S-3 (File No. 333-134688) on June 1, 2006 covering the resale of share of common stock subject to purchase pursuant to the warrants, and the warrants were issued pursuant to Rule 506 promulgated under Regulation D.

On November 10, 2005, we completed an underwritten public offering of 5,720,000 shares of common stock, including 720,000 shares subject to the underwriters' over-allotment option at a public offering price of \$6.25 per share and realized aggregate proceeds of \$35.7 million. The offering was made pursuant to the Registration Statement on Form S-3 (File No. 333-127930) filed on August 29, 2005 with the Securities and Exchange Commission and the related prospectus supplement dated October 10, 2005.

On February 24, 2004, we completed our initial public offering of 6,900,000 shares of common stock, including 900,000 shares subject to the underwriters' over-allotment option at a