

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:
None

Name of Each Exchange on Which Registered:
None

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

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

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

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

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

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
(Do not check if a smaller reporting company)

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 or 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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DYNVAX TECHNOLOGIES CORPORATION

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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” or the negative of 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.

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.

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.

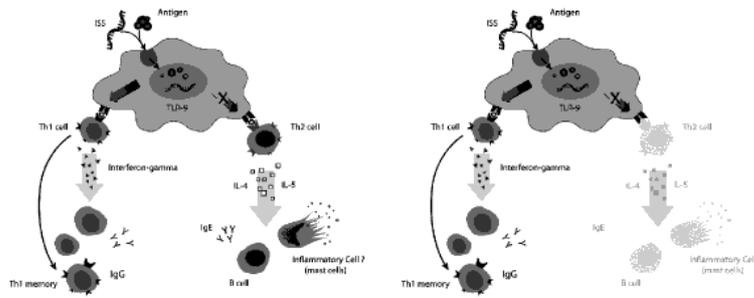
Influenza Vaccine

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.



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.

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

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.

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

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.

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

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 to 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 Rituxan™ (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

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.

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

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,

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.

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

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

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

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

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

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.

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;

- 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.

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

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.

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;

- 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.

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.

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

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 public offering price of \$7.50 per share and realized aggregate proceeds of \$51.8 million. Our registration statement on Form S-1 (Reg. No. 333-109965) was declared effective by the Securities and Exchange Commission on February 11, 2004.

We retain broad discretion over the use of the net proceeds received from our offerings. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product candidate development and commercialization efforts and the amount of cash used by our operations.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, and with the Consolidated Financial Statements and Notes thereto which are included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2007, 2006 and 2005 and the Consolidated Balance Sheets Data as of December 31, 2007 and 2006 are derived from the audited Consolidated Financial Statements included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2004 and 2003 and the Consolidated Balance Sheets Data as of December 31, 2005, 2004 and 2003 are derived from Consolidated Financial Statements that are not included in this Form 10-K. Historical results are not necessarily indicative of results to be anticipated in the future.

	Years Ended December 31,				
	2007(1)	2006(1)	2005	2004	2003
(In thousands, except per share data)					
Consolidated Statements of Operations Data:					
Total revenues	\$ 14,093	\$ 4,847	\$ 14,655	\$ 14,812	\$ 826
Operating expenses:					
Research and development(3)	65,888	50,116	27,887	23,129	13,786
General and administrative	18,293	14,836	9,258	8,543	4,804
Acquired in-process research and development(2)	—	4,180	—	—	—
Amortization of intangible assets	1,004	698	—	—	—
Total operating expenses	85,185	69,830	37,145	31,672	18,590
Loss from operations	(71,092)	(64,983)	(22,490)	(16,860)	(17,764)
Interest and other income, net	4,165	3,287	2,125	919	412
Interest expense	(1,719)	(99)	(190)	(30)	—
Deemed dividend	—	—	—	—	(633)
Loss including noncontrolling interest in Symphony Dynamo, Inc.	\$ (68,646)	\$ (61,795)	\$ (20,555)	\$ (15,971)	\$ (17,985)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	8,675	9,743	—	—	—
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)	\$ (15,971)	\$ (17,985)
Basic and diluted net loss per share	\$ (1.51)	\$ (1.61)	\$ (0.79)	\$ (0.75)	\$ (10.04)
Shares used in computing basic and diluted net loss per share	39,746	32,339	25,914	21,187	1,791

- (1) Our net loss for the years ended December 31, 2007 and December 31, 2006 includes approximately \$3.5 million and \$3.2 million, respectively, in stock-based compensation expense for our employee stock option and employee stock purchase plans that we recorded as a result of adopting Statement of Financial Accounting Standards No. 123R, "Share-Based Compensation."
- (2) Represents acquired in-process research and development. The amount for 2006 relates to the Rhein Biotech GmbH acquisition. For description of these charges, see Note 6 to the Consolidated Financial Statements.
- (3) Research and development expenses for the year ended December 31, 2007 include an impairment charge of approximately \$0.4 million for certain intangible assets and related inventory. For a description of these charges, see Note 6 to the Consolidated Financial Statements.

	December 31,				
	2007	2006	2005	2004	2003
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	\$ 56,617	\$ 72,831	\$ 75,110	\$ 65,844	\$ 29,097
Investments held by Symphony Dynamo, Inc.	31,631	13,363	—	—	—
Working capital	82,035	75,985	71,941	64,017	26,340
Total assets	120,449	102,890	80,093	73,646	31,585
Noncontrolling interest in Symphony Dynamo, Inc.	8,341	2,016	—	—	—
Minority interest in Dynavax Asia	—	—	—	—	14,733
Convertible preferred stock	—	—	—	—	83,635
Accumulated deficit	(227,914)	(167,943)	(115,891)	(95,336)	(79,365)
Total stockholders' equity (net capital deficiency)	30,790	77,056	74,363	59,876	(71,932)

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. The discussion should be read in conjunction with "Item 6 — Selected Financial Data" and the Consolidated Financial Statements and the related notes thereto set forth in "Item 8 — Financial Statements and Supplementary Data."

Overview

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

Our product candidates include: HEPLISAV™, a hepatitis B vaccine in Phase 3 partnered with Merck & Co., Inc.; TOLAMBA™, 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. 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 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

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.

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 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.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, research and development activities, stock-based compensation, investments, asset impairment, the estimated useful life of assets, income taxes and contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to the consolidated financial statements, we believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenues derive from collaborative agreements as well as grants. Collaborative agreements may include upfront license payments, cost reimbursement for the performance of research and development, milestone payments, contract manufacturing services, and royalty fees. In accordance with SAB 104, we

recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under the provisions of EITF 00-21. The different elements of the revenue arrangement are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where we have continuing performance obligations is deferred and recognized as performance occurs. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Revenue from milestones that are contingent upon the achievement of substantive at-risk performance criteria is recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services, and non-cash stock-based compensation. Research and development costs are expensed as incurred. For agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities entered into prior to January 1, 2008, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables. Agreements entered into after January 1, 2008 will be evaluated under the provisions of EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" which will require the Company to defer and capitalize costs related to non-refundable advance payments for goods or services to be received in the future for use in research and development activity. The capitalized amounts will be expensed as the related goods are delivered or services are performed. We do not expect this pronouncement to have a material effect on our consolidated financial statement.

Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical

trial or similar conditions. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties.

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, "Share-Based Payment," or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." We have elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects, if any, of stock-based compensation expense pursuant to FAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of FAS 123R.

As a result of the adoption of FAS 123R, we reduced our deferred stock compensation balance and additional paid in capital by \$2.5 million as of January 1, 2006. As of December 31, 2007, the total unrecognized compensation cost related to unvested options granted amounted to \$6.8 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.6 years.

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option's vesting period, assuming an annual forfeiture rate of 11%, and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected forfeiture rate, expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 5 years. Non-executive level employees were found to have historical option exercise and termination behavior that resulted in an expected life of 4 years. Expected volatility is based on historical volatility of our stock and comparable peer data over the life of the options granted to executive and non-executive level employees.

Acquired In-process Research and Development

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To determine the value of the acquired in-process research and development associated with the Rhein Biotech GmbH transaction, we used the income approach and the cost approach. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for distribution to the investors in the asset. We performed a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process research and development is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

Goodwill and Other Intangible Assets

Goodwill amounts are recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method of accounting. The valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. The Company operates in one segment and we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired as required by SFAS No. 142, "Goodwill and Other Intangible Assets."

Impairment of Long-lived Assets

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

- significant changes in the strategy for our overall business;
- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of acquired assets;
- significant negative industry or economic trends;
- significant decline in our stock price for a sustained period; and
- our market capitalization relative to net book value.

Determination of recoverability is based on an estimate of undiscounted cash flows resulting from the use of the asset and its eventual disposition. Measurement of impairment charges for long-lived assets that management expects to hold and use are based on the fair value of such assets.

Consolidation of Variable Interest Entities

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 material agreements included:

- the Amended and Restated Limited Liability Corporation Agreement of Symphony Dynamo Holdings LLC (LLC Agreement);
- the Funding Agreement by and among Dynavax Technologies Corporation, Symphony Capital Partners LP, Symphony Dynamo Holdings LLC, and Symphony Dynamo Investors LLC (Funding Agreement);
- the Amended and Restated Research and Development Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (R&D Agreement);
- the Novated and Restated Technology License Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (License Agreement);
- the Purchase Option Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (Purchase Option Agreement);
- the Registration Rights Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Registration Rights Agreement); and

- the Warrant Purchase Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Warrant Agreement).

The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC (Holdings) and its wholly-owned subsidiary SDI. Pursuant to the Funding Agreement, Symphony invested \$50.0 million in Holdings (\$20.0 million at closing and an additional \$30.0 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, which Holdings distributed to Symphony. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model. In consideration for the warrant, 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 that range from \$74.7 million at the end of the second year of the arrangement, increasing quarterly up to \$144.1 million at the fifth anniversary. 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.

SDI is governed by a separate board of directors, which is comprised of 5 members. Our CEO serves as a board member and we have the right to approve the two independent directors serving on the board. Additionally, our Vice President of Clinical Development serves as the chairman of the SDI joint development committee, which is responsible for overseeing and monitoring the Development Programs for which we have been contracted to perform services.

Under FASB Interpretation No. 46 (FIN 46R), "Consolidation of Variable Interest Entities," a variable interest entity (VIE) is (1) an entity that has equity that is insufficient to permit the entity to finance its activities without additional subordinated financial support, or (2) an entity that has equity investors that cannot make significant decisions about the entity's operations or that do not absorb their proportionate share of the expected losses or do not receive the expected residual returns of the entity. FIN 46R requires a VIE to be consolidated by the party that is deemed to be the primary beneficiary, which is the party that has exposure to a majority of the potential variability in the VIE's outcomes. The application of FIN 46R to a given arrangement requires significant management judgment.

We have consolidated the financial position and results of operations of SDI in accordance with FIN 46R. We have not consolidated Holdings because we believe our variable interest, the Purchase Option, is on the stock of SDI. We believe SDI is a VIE because we have the Purchase Option to acquire its outstanding voting stock at prices that were fixed upon entry into the arrangement, with the specific price based upon the date the option is exercised. The fixed nature of the Purchase Option price limits Symphony's returns, as the investor in SDI.

FIN 46R deems parties to be de facto agents if they cannot sell, transfer, or encumber their interests without the prior approval of an enterprise. Symphony is considered to be a de facto agent of the Company pursuant to this provision, and because we and Symphony as a related party group absorb a majority of SDI's variability, we evaluated whether, pursuant to FIN 46R's requirements, we are most closely associated with SDI. We concluded that we are most closely associated with SDI and should consolidate SDI because (1) we

originally developed the technology that was assigned to SDI, (2) we will continue to oversee and monitor the Development Programs, (3) our employees will continue to perform substantially all of the development work, (4) we significantly influenced the design of the responsibilities and management structure of SDI, (5) SDI's operations are substantially similar to our activities, and (6) through the Purchase Option, we have the ability to participate in the benefits of a successful development effort.

Symphony will be required to absorb the development risk for its equity investment in SDI. Pursuant to FIN 46R's requirements, Symphony's equity investment in SDI is classified as noncontrolling interest in the consolidated balance sheet. The noncontrolling interest held by Symphony has been reduced by the \$5.6 million fair value of the warrants it received and \$2.6 million of fees we immediately paid to Symphony upon the transaction's closing because the total consideration provided by us to Symphony effectively reduces Symphony's at-risk equity investment in SDI. While we perform the research and development on behalf of SDI, our development risk is limited to the consideration we provided to Symphony (the warrants and fees). We exercised the Program Option in April 2007, which resulted in the recognition of a \$15.0 million liability to Symphony. The noncontrolling interest was further reduced for this obligation as it will be paid to Symphony at the expiration of the SDI collaboration in 2011 if we do not exercise the Purchase Option, or will be included as part of the applicable purchase price upon exercise of the Purchase Option.

Net losses incurred by SDI are charged to the noncontrolling interest until that balance has been reduced to zero, at which point our net loss will be increased for the losses incurred by SDI subsequent to that date. At December 31, 2007, the noncontrolling interest balance was \$8.3 million, which we currently expect to be exhausted by the end of 2008. As of December 31, 2007, the investments held by SDI were \$31.6 million, which we expect will be spent on the Development Programs through the term of the collaboration in 2011.

If we do not exercise the Purchase Option, we would remain obligated to pay Symphony \$15.0 million for the Program Option, which we have reflected as a liability at December 31, 2007. Furthermore, if the Purchase Option expires unexercised, we would then be required to deconsolidate SDI. That potential deconsolidation would not be expected to impact our earnings because the carrying value of the net assets of SDI would be expected to be zero.

In contrast, if we exercise the Purchase Option, we will gain control of SDI. As such, we would expect to record the exercise of the Purchase Option as a return to the noncontrolling interest. We do not expect to recognize an asset for the Purchase Option payment to be made to Symphony. Instead, the payment is expected to be accounted for as a capital transaction that would not affect our net income or loss. However, because the exercise of the Purchase Option will be accounted for as a capital transaction, it will be treated as a deemed dividend for purposes of reporting earnings per share, increasing loss per share or decreasing income per share, as the case may be, in the period we exercise the Purchase Option. If the Development Programs are successful and the resources are available, we currently expect to exercise the Purchase Option.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants, services and license fees. Collaboration revenue includes revenue recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Services and license fees include research and development and contract manufacturing services, license fees and royalty payments.

The following is a summary of our revenues for the years ended December 31, 2007, 2006 and 2005 (in thousands, except for percentages):

Revenues:	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
Collaboration revenue	\$ 9,315	\$ 1,557	\$ 12,199	\$ 7,758	498%	\$ (10,642)	(87)%
Grant revenue	3,046	1,549	2,456	1,497	97%	(907)	(37)%
Services and license revenue	1,732	1,741	—	(9)	(1)%	1,741	—
Total revenues	<u>\$ 14,093</u>	<u>\$ 4,847</u>	<u>\$ 14,655</u>	<u>\$ 9,246</u>	191%	<u>\$ (9,808)</u>	(67)%

Total revenues for the year ended December 31, 2007 increased by \$9.2 million, or 191%, over the same period in 2006 primarily due to an increase in revenue recognized from our collaboration arrangements with Merck and AstraZeneca, which we entered into in October 2007 and September 2006, respectively. Grant revenue for the year ended December 31, 2007 included an increase of \$0.6 million associated with our National Institutes of Health (NIH) awards, following the resolution of a vendor restriction. In addition, the Company was awarded a two-year \$3.25 million grant in August 2007 from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the NIH, to continue development of a novel universal influenza vaccine. The Company recognized approximately \$0.5 million for the year ended December 31, 2007 relating to this grant. Services and license revenue of \$1.7 million was derived primarily from R&D services provided to customers of Dynavax Europe.

Collaboration revenue for the year ended December 31, 2006 decreased by \$10.6 million, or 87%, over the same period in 2005. Collaboration revenue for the year ended December 31, 2005 included an acceleration of revenue recognition of \$7.0 million resulting from the termination of our collaboration with UCB in March 2005. Grant revenue for the year ended December 31, 2006 decreased by \$0.9 million, or 37%. Grant revenue for the year ended December 31, 2005 included \$0.5 million associated with an adjustment to the final approved indirect cost rate utilized for our NIH awards.

We anticipate that our revenues will increase significantly in 2008 as compared to 2007 due primarily to our collaboration with Merck. Depending upon the resolution of the HEPLISAV clinical hold by the FDA, there could be an impact on the timing of the Merck-related revenues, including the recognition of the upfront payment and future development cost reimbursement.

Research and Development

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

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

Research and Development:	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
Compensation and related personnel costs	\$ 19,170	\$ 13,006	\$ 8,563	\$ 6,164	47%	\$ 4,443	52%
Outside services	38,726	31,042	15,084	7,684	25%	15,958	106%
Facility costs	6,414	4,988	3,673	1,426	29%	1,315	36%
Impairment	444	—	—	444	100%	—	—
Non-cash stock-based compensation	1,134	1,080	567	54	5%	513	90%
Total research and development	<u>\$ 65,888</u>	<u>\$ 50,116</u>	<u>\$ 27,887</u>	<u>\$ 15,772</u>	31%	<u>\$ 22,229</u>	80%

Research and development expenses for the year ended December 31, 2007 increased by \$15.8 million, or 31%, over the same period in 2006. The increase from fiscal 2006 was primarily due to outside services which included a non-recurring \$5 million payment in June 2007 for a non-exclusive license to certain patents and patent applications for the purpose of commercializing HEPLISAV. The remaining growth in outside services was due to increased clinical trial costs related to our product candidates HEPLISAV and TOLAMBA and expenses incurred to support SDI programs and Dynavax Europe operations. Compensation and related personnel costs increased in 2007 due to continued organizational growth to further develop our clinical candidates and the impact of a full year of operations from Dynavax Europe. Facility costs increased primarily due to rent expense for Dynavax Europe and higher operating costs in the U.S.

Research and development expenses for 2007 also included approximately \$0.4 million of impairment charges related to the Supervax program. In 2006, we acquired the Supervax hepatitis B vaccine manufactured by Dynavax Europe. Supervax was launched in Argentina in December 2006 and was approved for marketing and sales through a third party distributor. We recorded immaterial revenues and expenses related to the manufacture and sale of formulated bulk vaccine in 2006 to the third party distributor. During the fourth quarter of 2007, we were notified that the distributor was unable to meet its annual commitment to order additional bulk vaccine due to its inability to sell all of the previously purchased Supervax product in the Argentine market. The underperformance of the Supervax program relative to originally expected future sales caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. As a result, we determined that estimated future cash flows from sales of Supervax were significantly less than the projection established at the time of acquisition, and we considered this an indicator of impairment. As of November 2007, we performed our impairment test of long-lived assets. Based on our analysis, the fair value of the acquired intangible asset (developed technology) and inventory associated with the Supervax program was estimated to be zero; therefore, we recorded a permanent write down of these assets in accordance with SFAS No. 144.

Research and development expenses for the year ended December 31, 2006 increased by \$22.2 million, or 80%, from the same period in 2005. The increase from fiscal year 2005 was primarily due to increased clinical trial and clinical material manufacturing costs for our product candidates TOLAMBA and HEPLISAV, as well as expenses incurred to support the SDI programs and Dynavax Europe operations. Outside services during the period also included approximately \$0.1 million of costs associated with the manufacture of Supervax formulated bulk vaccine. Compensation and related personnel costs increased in 2006 due to continued organizational growth to further develop our clinical candidates and the acquisition of Dynavax Europe. Facility costs increased primarily due to rent expense for Dynavax Europe. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

We anticipate that our research and development expenses will increase significantly in 2008 as compared to 2007, primarily in connection with the advancement of HEPLISAV, TOLAMBA and other programs.

General and Administrative

General and administrative expenses consist primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance; legal costs that include corporate and patent expenses, net of patent cost recoveries; allocated facility costs; and

non-cash stock-based compensation. The following is a summary of our general and administrative expense (in thousands, except for percentages):

General and Administrative:	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
	Compensation and related personnel costs	\$ 7,101	\$ 6,264	\$ 4,426	\$ 837	13%	\$ 1,838
Outside services	5,248	4,008	2,372	1,240	31%	1,636	69%
Legal costs	2,951	1,727	1,117	1,224	71%	610	55%
Facility costs	610	591	510	19	3%	81	16%
Other	—	43	—	(43)	(100)%	43	—
Non-cash stock-based compensation	2,383	2,203	833	180	8%	1,370	164%
Total general and administrative	\$ 18,293	\$ 14,836	\$ 9,258	\$ 3,457	23%	\$ 5,578	60%

General and administrative expenses for the year ended December 31, 2007 increased by \$3.5 million, or 23%, over the same period in 2006. The increase primarily reflects additional legal costs associated with patent activities. Compensation and related personnel costs increased in 2007 as a result of overall organizational growth including the operations of Dynavax Europe. Outside services increased in 2007 related to higher professional fees incurred to support various corporate development activities, SDI programs and Dynavax Europe operations.

General and administrative expenses for the year ended December 31, 2006 increased by \$5.6 million, or 60%, over the same period in 2005. The increase from fiscal 2005 primarily reflects additional compensation and related personnel costs associated with overall organizational growth, including the impact of Dynavax Europe. Outside services and legal costs increased in 2006 related to higher accounting fees, consulting fees incurred in conjunction with various corporate development activities, and expenses incurred to support SDI programs and Dynavax Europe operations. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

We expect general and administrative expenses to increase modestly in 2008 as compared to 2007, resulting from continued organizational growth and expenses incurred to support corporate development activities.

Acquired In-process Research and Development

Following our April 2006 acquisition of Rhein Biotech GmbH (Rhein), we recorded the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. As a result, we recorded net tangible assets of \$3.0 million, goodwill of \$2.3 million, other intangible assets of \$5.1 million, and expense associated with the acquired in-process research and development of \$4.2 million, representing the fair value of research projects that had not yet reached technological feasibility and that have no alternative future use.

A summary of the acquired in-process research and development programs, and of the value assigned and recognized as expense as of the acquisition date is as follows (in thousands):

Program	Description	Estimated Acquisition Date Fair Value
Supervax	A hepatitis B vaccine launched in Argentina in December 2006 and approved for marketing and sales through a third party distributor.	\$ 890
Theravax	A potential therapeutic treatment of chronic Hepatitis B infection.	2,740
Cytovax	A potential prophylactic vaccine to prevent infection from cytomegalovirus.	550
		<u>\$ 4,180</u>

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Supervax program was determined using the income approach, which discounts expected future cash flows

to present value. We estimated the related future net cash flows between 2006 and 2020 and discounted them to their present value using a risk-adjusted discount rate of 50%, which was based on the estimated internal rate of return for Rhein's operations and was comparable to the estimated weighted average cost of capital for companies with Rhein's profile. The projected cash flows from the Supervax program were based on key assumptions such as estimates of revenues and operating profits related to the program considering its stage of development; the time and resources needed to complete the development and approval of the related product; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Given the high risk associated with the development of new drugs, we adjusted the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process.

From the acquisition date through the year ended December 31, 2006, we continued registration activities for Supervax in territories other than Argentina. Actual sales for the fiscal year ended 2006 of Supervax in Argentina, while immaterial, were substantially in accordance with the original projections at the valuation date. During fiscal year 2007, we continued to monitor sales of Supervax in Argentina and we continued efforts to market Supervax in order to determine if we could achieve planned regulatory approvals in other markets. However, the lack of performance of the Supervax program under our distribution arrangement caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. For the year ended December 31, 2007, we recorded an impairment charge of \$0.4 million to write off the intangible asset and inventory associated with the Supervax program.

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Theravax and Cytovax programs was determined using the cost approach. We considered the stage of product development and the nature of these projects. At the valuation date, both Theravax and Cytovax were in early stages of development and were many years away from obtaining regulatory approval, if at all, and the risks associated with identifying material cash flows as well as the nature, timing and projected costs associated with the remaining efforts for completion of the projects were not reasonably estimable. However, we were able to estimate the cost involved in recreating the technology using historical data from Rhein, including cost and effort applied to the development of the technology prior to the acquisition date. We did not anticipate significant cash inflows for Theravax or Cytovax. Significant appraisal assumptions included historical data related to personnel effort, costs associated with those efforts, and external costs in order to estimate the fair value of these products as of the acquisition date.

We intend to continue further development of a therapy to treat chronic hepatitis B infection. In March 2007, we initiated a Phase 1 clinical study of our hepatitis B therapeutic candidate in 20 healthy subjects. In early 2007, we made a strategic decision to discontinue development of Cytovax in order to focus on other opportunities in our product pipeline; however, due to the early stage of development, there was no impact to our results of operations and financial condition.

Amortization of Intangible Assets

Intangible assets consist primarily of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was \$1.0 million for the year ended December 31, 2007 compared to \$0.7 million for the same period in 2006.

Interest and Other Income, Net and Interest Expense

Interest income is reported net of amortization on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily

with Dynavax Europe and gains and losses on disposals of property and equipment. The following is a summary of our interest and other income, net (in thousands, except for percentages):

	Years Ended December 31,			Increase (Decrease) from 2006 to 2007		Increase (Decrease) from 2005 to 2006	
	2007	2006	2005	\$	%	\$	%
	Interest and other income, net	\$ 4,165	\$3,287	\$2,125	\$ 878	27%	\$1,162
Interest expense	\$(1,719)	\$ (99)	\$ (190)	\$1,620	1,636%	\$ (91)	(48%)

Interest and other income, net for the year ended December 31, 2007 increased by \$0.9 million, or 27%, over the same period in 2006. The increase reflects additional interest earned on the investments held by SDI and the investment of proceeds from upfront fees received in the fourth quarter of 2007. Interest expense for the year ended December 31, 2007 increased by \$1.6 million, or 1,636%, over the same period in 2006 due to interest expense incurred from the commitment fees and warrants issued under the Deerfield financing agreement. Interest and other income, net for the year ended December 31, 2006 increased by \$1.2 million, or 55%, over the same period in 2005. The increase was primarily caused by interest earned on the investments held by SDI of approximately \$0.5 million and the investment of proceeds from our financing activities in the fourth quarter of 2006.

Amount Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.

Pursuant to the agreements that we entered into with SDI in April 2006 and, in accordance with FIN 46R, the results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006. In accordance with FIN 46R, we have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated statements of operations, and we will continue to deduct such losses until the carrying amount of the noncontrolling interest in the consolidated balance sheet is reduced to zero. For the fiscal years ended December 31, 2007 and 2006, the losses attributed to the noncontrolling interest were \$8.7 million and \$9.7 million, respectively.

Recent Accounting Pronouncements

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" (Issue 07-3), which addressed the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008. We do not expect this Issue to have a material effect on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), "The Fair Value Option for Financial Assets and Financial Liabilities", which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 159 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the

information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Financial Interpretation No. 48 "Accounting for Uncertainty in Income Taxes" (FIN 48). We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of December 31, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2008.

Liquidity and Capital Resources

As of December 31, 2007, we had \$56.7 million in cash, cash equivalents and marketable securities and \$31.6 million in investments held by SDI. Our funds are currently invested in a variety of securities, including highly liquid institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

We have financed our operations since inception primarily through the sale of shares of our common stock, shares of our convertible preferred stock, and ordinary shares in a subsidiary, which have yielded a total of approximately \$222 million in net cash proceeds. To a lesser extent, we have financed our operations through amounts received under collaborative agreements and government grants. We have also financed certain of our research and development activities under our agreements with SDI and Deerfield.

We completed an initial public offering in February 2004, raising net proceeds of approximately \$46.5 million from the sale of 6,900,000 shares of common stock. In the fourth quarter of 2005, we completed an underwritten public offering that resulted in net proceeds of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. In the fourth quarter of 2006, we completed a follow-on offering raising approximately \$29.3 million from the sale of 7,130,000 shares of common stock.

In August 2006 we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd. Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of \$30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the 18-month term of the purchase agreement. From time to time over the term of the purchase agreement, and at our sole discretion, we may present Azimuth with draw down notices constituting offers to purchase our common stock. The per share purchase price for these shares is at a discount ranging from 5.2% to 7.0%. In December 2006, we completed a draw down on our equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of our common stock. A total of \$15 million remains available on our equity line of credit through the extended term of the agreement, which is December 31, 2008.

In July 2007, Deerfield committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loan principal for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, we have no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. If all milestones are successfully achieved, Deerfield would receive warrants for the purchase of up to a total of 5,550,000 shares of the

Company's common stock during the term of the loan agreement. As of December 31, 2007, we issued 3,550,000 warrants to Deerfield, and \$5.5 million remained outstanding under the loan agreement.

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 during the fourth quarter 2007, 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.

Cash used in operating activities of \$32.0 million during the year ended December 31, 2007 compared to \$37.2 million for the same period in 2006. The decrease in cash usage over the prior year was due primarily to receipt of \$31.5 million in upfront fees from our collaboration with Merck, offset by our net loss and the amount attributed to the noncontrolling interest in SDI. Cash used in operating activities during 2006 increased from 2005 primarily due to the increase in cash usage over the prior year was due primarily to the increase in our net loss from operations and the increase in working capital, offset by the receipt of \$10.0 million in upfront fees from our collaboration with AstraZeneca.

Cash used in investing activities of \$3.6 million during the year ended December 31, 2007 compared to \$20.4 million for the same period in 2006. The decrease was attributed to the net proceeds from maturities of marketable securities. Cash used in investing activities during 2006 increased from 2005 due to \$14.0 million in cash paid to acquire Rhein and \$13.4 million in purchases of investments held by SDI, net of proceeds from sales of marketable securities.

Cash provided by financing activities of \$35.7 million during the year ended December 31, 2007 compared to \$62.9 million for the same period in 2006. Cash provided by financing activities primarily included \$30 million in proceeds from the purchase of the noncontrolling interest in SDI and \$5.5 million in loan proceeds from Deerfield. Cash provided by financing activities during 2006 increased from 2005 primarily due to proceeds from equity offerings and \$17.4 million in proceeds from the purchase of the noncontrolling interest in SDI, net of fees.

We currently anticipate that our cash and marketable securities, collaboration agreements, investments held by SDI, available funds under our Azimuth equity line of credit, and Deerfield financing arrangement will enable us to maintain our operations for at least the next twelve months. Because of the significant time it will take for any of our product candidates to complete clinical trials, achieve regulatory approval and generate significant revenue, we will require substantial additional capital resources. We may raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations.

Additional financing may not be available on acceptable terms, if at all and therefore may adversely affect our ability to operate as a going concern. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, fail to meet the diligence obligations under existing licenses or enter into collaborative arrangements at an earlier stage of development on less favorable terms than we would otherwise choose.

Contractual Obligations

The following summarizes our significant contractual obligations as of December 31, 2007 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
Future minimum payments under our operating lease, excluding payments from the sublease agreement	\$ 22,596	\$ 2,073	\$ 7,780	\$ 5,548	\$ 7,195
Long-term liability from the program option exercised under the SDI collaboration	15,000	—	—	15,000	—
Future commitment fees under our financing agreement with Deerfield	4,512	1,770	2,742	—	—
Long-term liability from Deerfield financing agreement	5,500	—	5,500	—	—
Total	\$ 47,608	\$ 3,843	\$ 16,022	\$ 20,548	\$ 7,195

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in September 2009 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$25 thousand through 2007 and \$55 thousand annually thereafter until August 2010. The sublease rental income is offset against rent expense.

In April 2007, we exercised an option to repurchase our hepatitis B program from SDI. The exercise of the program option triggered a payment obligation of \$15 million which will be due upon the expiration of the SDI collaboration in 2011, if the purchase option for all programs is not exercised. The price for the program option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the purchase option.

As of December 31, 2007, we have drawn down \$5.5 million from the Deerfield financing agreement in which the outstanding principal will be due in July 2010.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

In October 2007, we entered into a manufacturing agreement with Merck for the supply of hepatitis B surface antigen. Under the terms of the agreement, 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.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and

development programs. Under the terms of the agreements, we may be required to pay future upfront fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 million through 2012. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. As of December 31, 2007, such fees and milestone payments to the Regents could approximate \$1 million in 2008.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC and Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have a current or future effect on our financial position. As described above, SDI is considered a variable interest entity and included in our financial statements. Our financing arrangement with SDI does not qualify as an off-balance sheet arrangement as defined by applicable SEC regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosure About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

Interest Rate Risk. We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk. We have certain investments outside the U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2007 was \$0.3 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

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Report of Independent Registered Public Accounting Firm

To The Board of Directors and Stockholders
Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dynavax Technologies Corporation at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, under the heading Stock-Based Compensation, in 2006 Dynavax Technologies Corporation changes its method of accounting for stock-based compensation.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2008, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Francisco, California
March 13, 2008

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

	December 31,	
	2007	2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,293	\$ 14,154
Marketable securities	42,324	58,677
Investments held by Symphony Dynamo, Inc. (SDI)	31,631	13,363
Restricted cash	408	408
Accounts receivable	7,234	2,154
Inventory	—	257
Prepaid expenses and other current assets	6,049	673
Total current assets	101,939	89,686
Property and equipment, net	7,314	5,200
Goodwill	2,312	2,312
Other intangible assets, net	3,239	4,382
Other assets	5,645	1,310
Total assets	<u>\$ 120,449</u>	<u>\$ 102,890</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,418	\$ 2,181
Accrued liabilities	12,059	10,742
Deferred revenues	3,427	778
Total current liabilities	19,904	13,701
Deferred revenues, noncurrent	40,792	10,000
Liability from program option exercised under the SDI collaboration	15,000	—
Other long-term liabilities	5,622	117
Noncontrolling interest in SDI	8,341	2,016
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at December 31, 2007 and 2006	—	—
Common stock: \$0.001 par value; 100,000 shares authorized at December 31, 2007 and 2006; 39,765 and 39,715 shares issued and outstanding at December 31, 2007 and 2006, respectively	40	40
Additional paid-in capital	258,266	244,787
Accumulated other comprehensive income:		
Unrealized gain on marketable securities available-for-sale	138	28
Cumulative translation adjustment	260	144
Accumulated other comprehensive income	398	172
Accumulated deficit	(227,914)	(167,943)
Total stockholders' equity	30,790	77,056
Total liabilities, noncontrolling interest and stockholders' equity	<u>\$ 120,449</u>	<u>\$ 102,890</u>

See accompanying notes.

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

	Years Ended December 31,		
	2007	2006	2005
Revenues:			
Collaboration revenue	\$ 9,315	\$ 1,557	\$ 12,199
Grant revenue	3,046	1,549	2,456
Service and license revenue	1,732	1,741	—
Total revenues	<u>14,093</u>	<u>4,847</u>	<u>14,655</u>
Operating expenses:			
Research and development	65,888	50,116	27,887
General and administrative	18,293	14,836	9,258
Acquired in-process research and development	—	4,180	—
Amortization of intangible assets	1,004	698	—
Total operating expenses	<u>85,185</u>	<u>69,830</u>	<u>37,145</u>
Loss from operations	(71,092)	(64,983)	(22,490)
Interest and other income, net	4,165	3,287	2,125
Interest expense	(1,719)	(99)	(190)
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(68,646)	(61,795)	(20,555)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	8,675	9,743	—
Net loss	<u>\$ (59,971)</u>	<u>\$ (52,052)</u>	<u>\$ (20,555)</u>
Basic and diluted net loss per share	<u>\$ (1.51)</u>	<u>\$ (1.61)</u>	<u>\$ (0.79)</u>
Shares used to compute basic and diluted net loss per share	<u>39,746</u>	<u>32,339</u>	<u>25,914</u>

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Deferred Stock Compensation	Notes Receivable From Stockholders	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
	Shares	Par Amount						
Balances at December 31, 2004	24,627	\$ 25	\$ 159,074	\$ (3,366)	\$ (419)	\$ (102)	\$ (95,336)	\$ 59,876
Issuance of common stock upon public offering	5,720	5	33,132	—	—	—	—	33,137
Exercise of stock options	113	—	19	—	—	—	—	19
Issuance of common stock under Employee Stock Purchase Plan	22	—	114	—	—	—	—	114
Interest accrued on notes receivable from stockholders	—	—	—	—	(16)	—	—	(16)
Repayment of notes receivable from stockholders	—	—	—	—	435	—	—	435
Deferred stock compensation	—	—	501	(501)	—	—	—	—
Amortization of deferred stock compensation	—	—	—	1,400	—	—	—	1,400
Comprehensive loss:								
Change in unrealized loss on marketable securities	—	—	—	—	—	(42)	—	(42)
Cumulative translation adjustment	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(20,555)	(20,555)
Comprehensive loss	—	—	—	—	—	—	—	(20,602)
Balances at December 31, 2005	30,482	30	192,840	(2,467)	—	(149)	(115,891)	74,363
Issuance of common stock upon equity offerings	8,794	9	44,032	—	—	—	—	44,041
Exercise of stock options	412	1	1,339	—	—	—	—	1,340
Issuance of common stock under Employee Stock Purchase Plan	27	—	114	—	—	—	—	114
Issuance of warrants in conjunction with Symphony Dynamo, Inc. transaction	—	—	5,646	—	—	—	—	5,646
Stock compensation expense	—	—	3,283	—	—	—	—	3,283
Reclassification of deferred stock compensation balance upon adoption of FAS 123R	—	—	(2,467)	2,467	—	—	—	—
Comprehensive loss:								
Change in unrealized gain on marketable securities	—	—	—	—	—	172	—	172
Cumulative translation adjustment	—	—	—	—	—	149	—	149
Net loss	—	—	—	—	—	—	(52,052)	(52,052)
Comprehensive loss	—	—	—	—	—	—	—	(51,731)
Balances at December 31, 2006	39,715	40	244,787	—	—	172	(167,943)	77,056
Exercise of stock options	6	—	22	—	—	—	—	22
Issuance of common stock under Employee Stock Purchase Plan	44	—	149	—	—	—	—	149
Proceeds from issuance of common stock, net of fees	—	—	(19)	—	—	—	—	(19)
Issuance of warrants in conjunction with Deerfield Financing Arrangement	—	—	9,796	—	—	—	—	9,796
Stock compensation expense	—	—	3,531	—	—	—	—	3,531
Comprehensive loss:								
Change in unrealized gain on marketable securities	—	—	—	—	—	110	—	110
Cumulative translation adjustment	—	—	—	—	—	116	—	116
Net loss	—	—	—	—	—	—	(59,971)	(59,971)
Comprehensive loss	—	—	—	—	—	—	—	(59,745)
Balances at December 31, 2007	39,765	\$ 40	\$ 258,266	\$ —	\$ —	\$ 398	\$ (227,914)	\$ 30,790

See accompanying notes.

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

	Years Ended December 31,		
	2007	2006	2005
Operating activities			
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,483	1,130	759
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc. (SDI)	(8,675)	(9,743)	—
Acquired in-process research and development	—	4,180	—
Amortization of intangible assets	1,004	698	—
(Gain) loss on disposal of property and equipment	—	(36)	—
Accretion and amortization on marketable securities	(1,855)	(296)	973
Realized loss (gain) on investments	—	23	(1)
Interest accrued on notes receivable from stockholders	—	—	(16)
Interest associated with Deerfield financing agreement	1,248	—	—
Stock-based compensation expense	3,531	3,283	1,400
Changes in operating assets and liabilities:			
Accounts receivable	(5,080)	(976)	2,442
Prepaid expenses and other current assets	(1,851)	604	119
Inventory	257	(257)	—
Other assets	1,269	(513)	(10)
Accounts payable	2,237	1,006	(439)
Accrued liabilities	930	5,847	(530)
Deferred revenues	33,441	9,862	(7,000)
Net cash used in operating activities	(32,032)	(37,240)	(22,858)
Investing activities			
Purchases of investments held by SDI	(18,268)	(13,363)	—
Cash paid for acquisition, net of cash acquired	—	(14,045)	—
Purchases of marketable securities	(80,232)	(65,842)	(84,014)
Proceeds from maturities of marketable securities	98,550	63,008	59,005
Proceeds from sales of marketable securities	—	10,987	6,864
Purchases of property and equipment	(3,647)	(1,125)	(562)
Net cash used in investing activities	(3,597)	(20,380)	(18,707)
Financing activities			
Proceeds from purchase of noncontrolling interest by shareholders in SDI, net of fees	30,000	17,405	—
Proceeds from notes payable issued to Deerfield	5,500	—	—
Proceeds from issuance of common stock, net of issuance costs	(19)	44,041	33,137
Exercise of stock options	22	1,340	19
Proceeds from employee stock purchase plan	149	114	114
Repayment of notes receivable from stockholders	—	—	435
Net cash provided by financing activities	35,652	62,900	33,705
Effect of exchange rate on cash and cash equivalents	116	149	(5)
Net increase (decrease) in cash and cash equivalents	139	5,429	(7,865)
Cash and cash equivalents at beginning of year	14,154	8,725	16,590
Cash and cash equivalents at end of year	<u>\$ 14,293</u>	<u>\$ 14,154</u>	<u>\$ 8,725</u>
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	\$ 356	\$ —	\$ —
Non-cash investing and financing activities:			
Liability from program option exercised under the SDI transaction	\$ 15,000	\$ —	\$ —
Warrants issued in conjunction with the SDI transaction	\$ —	\$ 5,646	\$ —
Warrants issued in conjunction with the Deerfield financing agreement	\$ 9,796	\$ —	\$ —
Disposal of fully depreciated property and equipment	\$ 238	\$ 395	\$ 60
Exercise of stock options	\$ —	\$ —	\$ 200
Repurchase of common stock for exercise of stock options	\$ —	\$ —	\$ (200)

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

Subsidiaries

In April 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, a wholly-owned subsidiary in Düsseldorf, Germany. Our wholly-owned subsidiary in Japan formed in December 2004, Ryden Therapeutics KK, was liquidated in the fourth quarter of 2006. Our wholly-owned subsidiary in Singapore formed in October 2003, Dynavax Asia Pte. Ltd., was liquidated in the fourth quarter of 2007.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries as well as the accounts of a variable interest entity, Symphony Dynamo, Inc. (SDI), which we consolidate pursuant to Financial Accounting Standards Board Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities," or FIN 46R. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

Use of Estimates

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

Foreign Currency

We consider the local currency to be the functional currency for our international subsidiaries. Accordingly, assets and liabilities denominated in foreign currencies are translated into U.S. dollars using the exchange rate on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the year. Currency translation adjustments are charged or credited to accumulated other comprehensive income (loss) in the consolidated balance sheets. Gains and losses resulting from currency transactions are included in the consolidated statements of operations.

Cash, Cash Equivalents, Marketable Securities and Investments held by Symphony Dynamo, Inc.

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Management determines the appropriate classification of marketable securities at the time of purchase. We invest in short-term commercial paper, money market funds, government and non-government debt securities and corporate obligations, which are subject to minimal credit and market risk. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity.

Investments held by SDI consist of investments in money market funds. As of December 31, 2007, we had investments held by SDI of \$31.6 million.

We have classified our entire investment portfolio as available-for-sale. We view our available-for-sale portfolio as available for use in current operations, and accordingly, have classified all investments as short-term. As of December 31, 2007 the stated maturity of our investments is within one year of the current balance sheet date. In accordance with SFAS 115, "Accounting for Certain Investments in Debt and Equity Securities," available-for-sale securities are carried at fair value based on quoted market prices, with unrealized gains and losses included in accumulated other comprehensive income in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

- Length of the time and the extent to which the market value has been less than cost;
- The financial condition and near-term prospects of the issuer; and
- Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

To date, there have been no declines in fair value that have been identified as other than temporary.

Fair Value of Financial Instruments

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that are subject to concentration of credit risk consist primarily of cash and cash equivalents, accounts receivable, and marketable securities. Our policy is to invest cash in institutional money market funds and marketable securities of U.S. government and corporate issuers with high credit quality in order to limit the amount of credit exposure. We have not experienced any losses on our cash and cash equivalents and marketable securities.

Trade accounts receivable are recorded at invoice value. We review our exposure to accounts receivable, including the potential for allowances based on management's judgment. We have not historically experienced any significant losses. We do not currently require collateral for any of our trade accounts receivable.

Our future products will require approval from the U.S. Food and Drug Administration and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals would have a material adverse impact on our consolidated financial position and results of operations.

We rely on a single contract manufacturer to produce material for certain of our clinical trials. The loss of our current supplier could delay development or commercialization of our product candidates. To date, we have manufactured only small quantities of material for research purposes.

We are subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, clinical development risk, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, product liability, and the need to obtain additional financing.

Inventory

Included in inventory at December 31, 2006 are raw materials and finished goods for a hepatitis B vaccine product. Inventory is stated at the lower of cost or market. Our inventory costs are determined using the first-in, first-out method.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. The assets held in the Berkeley facility have estimated useful lives of three years for computer equipment and furniture, and five years for laboratory equipment. The assets in the Düsseldorf, Germany facility have estimated useful lives of three years for computer equipment and thirteen years for furniture and laboratory equipment. Leasehold improvements in both facilities are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter. Repair and maintenance costs are charged to expense as incurred.

Long-lived Assets

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

- significant changes in the strategy for our overall business;
- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of acquired assets;
- significant negative industry or economic trends;
- significant decline in our stock price for a sustained period; and
- our market capitalization relative to net book value.

Recoverability is measured by comparison of the assets' carrying amounts to the future net undiscounted cash flows resulting from the use of the asset and its eventual disposition. If these assets are considered impaired, the impairment recognized is measured by the amount by which the carrying value of the assets exceed the projected discounted future net cash flows associated with the assets. For the year ended December 31, 2007, we recognized an impairment charge included in research and development expenses of \$0.4 million to write off the carrying amount of the intangible asset related to the Supravax developed technology acquired as part of the Rhein Biotech GmbH acquisition and related inventory (See Note 6).

Revenue Recognition

Our revenues derive from collaborative agreements as well as grants. Collaborative agreements may include upfront license payments, cost reimbursement for the performance of research and development, milestone payments, contract manufacturing services, and royalty fees. In accordance with SAB 104, we recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured. Our revenue arrangements that contain multiple elements are evaluated under the provisions of EITF 00-21. The different elements of the revenue arrangement are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where we have continuing performance obligations is deferred and recognized as performance occurs. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Revenue from milestones that are contingent upon the achievement of substantive at-risk performance criteria is recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been non-refundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

Revenue from government and private agency grants are recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services, and non-cash stock-based compensation. Research and development costs are expensed as incurred. For agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities entered into prior to January 1, 2008, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables. Agreements entered into after January 1, 2008 will be evaluated under the provisions of EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" which will require the Company to defer and capitalize costs related to non-refundable advance payments for good or services to be received in the future for use in research and development activity. The capitalized amounts will be expensed as the related goods are delivered or services are performed.

Our accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial or similar conditions. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties.

Acquired In-process Research and Development

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To determine the value of the acquired in-process research and development, or in-process R&D associated with the Rhein Biotech GmbH transaction discussed in Note 6, we used the income approach and the cost approach to value in-process research and development. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for

distribution to the investors in the asset. We performed a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. The cost approach is based on the theory that a prudent investor would pay no more than the cost of constructing a similar asset of like utility at prices applicable at the time of the appraisal. We estimate the costs involved in re-creating the technology using the historical cost and effort applied to the development of the technology prior to the valuation date. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process R&D is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

Goodwill and Other Intangible Assets

Goodwill amounts are recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method of accounting. The valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired as required by SFAS No. 142, "Goodwill and Other Intangible Assets."

Consolidation of Variable Interest Entities

Under FIN 46R, "Consolidation of Variable Interest Entities," arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities, or VIEs. An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

Based on the provisions of FIN 46R, we have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Our consolidated financial statements include the accounts of Symphony Dynamo, Inc., a variable interest entity, of which we are the primary beneficiary, as discussed in Note 8.

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, "Share-Based Payment," or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." We have elected to adopt the

alternative transition method provided in the FASB Staff Position for calculating the tax effects, if any, of stock-based compensation expense pursuant to FAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of FAS 123R.

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment and estimates. The fair value of each option is amortized on a straight-line basis over the option's vesting period, assuming an annual forfeiture rate of 11%, and is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions, including the expected forfeiture rate, expected life of the option and expected stock price volatility. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, were grouped and considered separately for valuation purposes, which resulted in an expected life of 5 years. Non-executive level employees were found to have historical option exercise and termination behavior that resulted in an expected life of 4 years. Expected volatility is based on historical volatility of our stock and comparable peer data over the life of the options granted to executive and non-executive level employees.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss), which includes certain changes in equity that are excluded from net loss. We include unrealized holding gains and losses on marketable securities and cumulative translation adjustments in accumulated other comprehensive loss.

Income Taxes

We account for income taxes using the liability method under FAS 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, we must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. We have provided a full valuation allowance on our deferred tax assets because we believe it is more likely than not that our deferred tax assets will not be realized. We evaluate the realizability of our deferred tax assets on a quarterly basis. Currently, there is no provision for income taxes as we have incurred losses to date.

Effective January 1, 2007, we adopted the provisions of FIN 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109." FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured and derecognized in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim-period guidance, among other provisions.

At the date of adoption of FIN 48, there was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of December 31, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2008.

Recent Accounting Pronouncements

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" (Issue 07-3), which addressed the accounting for nonrefundable advance payments. The EITF

concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008. We do not expect this Issue to have a material effect on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), "The Fair Value Option for Financial Assets and Financial Liabilities", which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 159 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008. We do not expect this pronouncement to have a material effect on our consolidated results of operations and financial condition.

3. Available-for-Sale Securities

The following is a summary of available-for-sale securities included in cash and cash equivalents, marketable securities, investments held by SDI and restricted cash as of December 31, 2007 and 2006 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2007:				
Certificates of deposit and money market funds	\$ 42,290	\$ —	\$ —	\$ 42,290
Corporate debt securities	44,684	140	(2)	44,822
Total	<u>\$ 86,974</u>	<u>\$ 140</u>	<u>\$ (2)</u>	<u>\$ 87,112</u>
December 31, 2006:				
Certificates of deposit and money market funds	\$ 26,795	\$ 1	\$ —	\$ 26,796
Corporate debt securities	58,650	27	—	58,677
Total	<u>\$ 85,445</u>	<u>\$ 28</u>	<u>\$ —</u>	<u>\$ 85,473</u>

There were no realized gains from the sale of marketable securities for the years ended December 31, 2007 and 2006. Realized losses from the sale of marketable securities were zero in 2007 and immaterial in 2006. As of December 31, 2007 and 2006, all of our investments are classified as short-term, as we have classified our investments as available-for-sale and may not hold our investments until maturity. As of December 31, 2007, our marketable securities had the following maturities (in thousands):

Maturities:	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 86,974	\$ 87,112
Total	<u>\$ 86,974</u>	<u>\$ 87,112</u>

4. Inventory

Inventory as of December 31, 2007 and 2006 consists of the following (in thousands):

	December 31, 2007	December 31, 2006
Raw Materials	\$ —	\$ 194
Finished Goods	—	63
Total	\$ —	\$ 257

5. Property and Equipment

Property and equipment as of December 31, 2007 and 2006 consist of the following (in thousands):

	December 31,	
	2007	2006
Laboratory equipment	\$ 12,824	\$ 9,984
Computer equipment	1,403	1,156
Furniture and fixtures	1,525	1,396
Leasehold improvements	2,810	1,968
	18,562	14,504
Less accumulated depreciation and amortization	(11,248)	(9,304)
Total	\$ 7,314	\$ 5,200

Depreciation and amortization expense on property and equipment was \$1.5 million, \$1.2 million and \$0.8 million for the years ended December 31, 2007, 2006, and 2005, respectively.

6. Acquisition of Rhein Biotech GmbH

On April 21, 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, from Rhein Biotech NV, a subsidiary of Berna Biotech AG, or Berna. As a result, the financial position and results of operations of Rhein have been included in our consolidated financial statements as of December 31, 2007 and for the period from April 22, 2006 through December 31, 2006. Rhein, located in Düsseldorf, Germany, became a wholly-owned subsidiary which we refer to as Dynavax Europe. Through this acquisition, we gained ownership of a certified current Good Manufacturing Practice, or GMP, vaccine manufacturing facility in the European Union, control over the production and supply of its hepatitis B surface antigen and potentially other antigens to support clinical and commercial programs, management and personnel with expertise in biopharmaceutical product development and production and a complementary pipeline of vaccine and antiviral products. Upon closing of the transaction, our license and supply agreement with Berna for the supply of hepatitis B surface antigen used in our HEPLISAV vaccine was terminated, eliminating Berna's option to commercialize HEPLISAV.

Under the terms of the transaction, we purchased all of the outstanding capital stock of Rhein, which included the satisfaction of outstanding debt and certain employee and acquisition costs for an aggregate purchase price of approximately \$14.6 million. The components of the purchase price are summarized in the following table (in thousands):

Consideration and acquisition costs:	
Cash paid for common stock	\$ 7,925
Cash paid to satisfy outstanding debt	4,550
Employee costs	745
Acquisition costs	1,338
Total purchase price	\$ 14,558

Under the purchase method of accounting, the total purchase price is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of the acquisition. Certain purchase accounting adjustments were made in order to state the tangible assets acquired and liabilities assumed at their estimated fair values and in accordance with our accounting policies and U.S. generally accepted accounting principles. These adjustments primarily impacted deferred revenue and acquired property and equipment. We assessed the fair value of the identifiable intangible assets acquired, as well as in-process research and development. Our methodology for allocating the purchase price to in-process R&D is determined through established valuation techniques in the biotechnology industry. In-process R&D is expensed upon acquisition because technological feasibility has not been established at that date and no future alternative uses exist. The purchase price was allocated using information available at the time of acquisition. The excess of purchase price over the aggregate fair values was recorded as goodwill.

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

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

Intangible assets consist primarily of manufacturing process, customer relationships, and developed technology. The manufacturing process derives from the methods for making proteins in *Hansenula yeast*, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. The developed technology derives from a licensed hepatitis B vaccine product called Supervax. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at December 31, 2007 and December 31, 2006 (in thousands, except years):

	Estimated Useful Life (In years)	December 31, 2007			December 31, 2006		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible Assets:							
Manufacturing process	5	\$ 3,670	\$ 1,244	\$ 2,426	\$ 3,670	\$ 509	\$ 3,161
Customer relationships	5	1,230	417	813	1,230	171	1,059
Developed technology	7	—	—	—	180	18	162
Total	5.1	\$ 4,900	\$ 1,661	\$ 3,239	\$ 5,080	\$ 698	\$ 4,382

The estimated future amortization expense of purchased intangible assets is as follows (in thousands):

Year ending December 31,	
2008	\$ 980
2009	980
2010	980
2011	299
Total	<u>\$ 3,239</u>

A summary of the acquired in-process research and development programs, and of the value assigned and recognized as expense as of the acquisition date is as follows (in thousands):

Program	Description	Estimated Acquisition Date Fair Value
Supervax	A hepatitis B vaccine launched in Argentina in December 2006 and approved for marketing and sales through a third party distributor.	\$ 890
Theravax	A potential therapeutic treatment of chronic Hepatitis B infection.	2,740
Cytovax	A potential prophylactic vaccine to prevent infection from cytomegalovirus.	550
		<u>\$ 4,180</u>

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Supervax program was determined using the income approach, which discounts expected future cash flows to present value. We estimated the related future net cash flows between 2006 and 2020 and discounted them to their present value using a risk-adjusted discount rate of 50%, which was based on the estimated internal rate of return for Rhein's operations and was comparable to the estimated weighted average cost of capital for companies with Rhein's profile. The projected cash flows from the Supervax program were based on key assumptions such as estimates of revenues and operating profits related to the program considering its stage of development; the time and resources needed to complete the development and approval of the related product; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Given the high risk associated with the development of new drugs, we adjusted the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process.

From the acquisition date through the year ended December 31, 2006, we continued registration activities for Supervax in territories other than Argentina. Actual sales for the fiscal year ended 2006 of Supervax in Argentina, while immaterial, were substantially in accordance with the original projections at the valuation date. During fiscal year 2007, we continued to monitor sales of Supervax in Argentina and we continued efforts to market Supervax in order to determine if we could achieve planned regulatory approvals in other markets. We recorded immaterial revenues and expenses related to the manufacture and sale of formulated bulk vaccine in 2006 to the third party distributor. During the fourth quarter of 2007, we were notified that the distributor was unable to meet its annual commitment to order additional bulk vaccine due to its inability to sell all of the previously purchased Supervax product in the Argentine market. The underperformance of the Supervax program relative to originally expected future sales caused us to discontinue our marketing efforts of Supervax in territories outside of Argentina. As a result, we determined that estimated future cash flows from sales of Supervax were significantly less than the projection established at the time of acquisition, and we considered this an indicator of impairment. As of November 2007, we performed our impairment test of long-lived assets. Based on our analysis, the fair value of the Supervax developed technology and related inventory was estimated to be zero; therefore, we recorded a permanent write down of these assets in accordance with SFAS No. 144. For the year ended December 31, 2007, we recognized an impairment charge included in

research and development expenses of \$0.4 million to write off the carrying amounts of the intangible asset of \$0.1 million and the related inventory of \$0.3 million.

At the time of the acquisition, the estimated fair value of the acquired in-process research and development for the Theravax and Cytovax programs was determined using the cost approach. We considered the stage of product development and the nature of these projects. At the valuation date, both Theravax and Cytovax were in early stages of development and were many years away from obtaining regulatory approval, if at all, and the risks associated with identifying material cash flows as well as the nature, timing and projected costs associated with the remaining efforts for completion of the projects were not reasonably estimable. However, we were able to estimate the cost involved in recreating the technology using historical data from Rhein, including cost and effort applied to the development of the technology prior to the acquisition date. We did not anticipate significant cash inflows for Theravax or Cytovax. Significant appraisal assumptions included historical data related to personnel effort, costs associated with those efforts, and external costs in order to estimate the fair value of these products as of the acquisition date.

We intend to continue further development of a therapy to treat chronic hepatitis B infection. In March 2007, we initiated a Phase 1 clinical study of our hepatitis B therapeutic candidate in 20 healthy subjects. In early 2007, we made a strategic decision to discontinue development of Cytovax in order to focus on other opportunities in our product pipeline; however, due to the early stage of development, there was no impact to our results of operations and financial condition.

7. Current Accrued Liabilities

Current accrued liabilities as of December 31, 2007 and 2006 consist of the following (in thousands):

	December 31,	
	2007	2006
Payroll and related expenses	\$ 2,892	\$ 1,598
Legal expenses	1,708	732
Third party scientific research expense	6,044	6,668
Other accrued liabilities	1,415	1,744
Total	\$ 12,059	\$ 10,742

8. Symphony Dynamo, Inc.

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 material agreements included:

- the Amended and Restated Limited Liability Corporation Agreement of Symphony Dynamo Holdings LLC (LLC Agreement);
- the Funding Agreement by and among Dynavax Technologies Corporation, Symphony Capital Partners LP, Symphony Dynamo Holdings LLC, and Symphony Dynamo Investors LLC (Funding Agreement);
- the Amended and Restated Research and Development Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (R&D Agreement);
- the Novated and Restated Technology License Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (License Agreement);
- the Purchase Option Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (Purchase Option Agreement);
- the Registration Rights Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Registration Rights Agreement); and

- the Warrant Purchase Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Warrant Agreement).

The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC (Holdings) and its wholly-owned subsidiary, Symphony Dynamo, Inc. (SDI). Pursuant to the Funding Agreement, Symphony invested \$50.0 million in Holdings (\$20.0 million at closing and an additional \$30.0 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock, which Holdings distributed to Symphony, at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share if either of two events occurs: (a) we enter into a collaboration agreement with a third party for a specified oncology program; or (b) the Purchase Option is terminated or expires unexercised. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model and was recorded in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option (Purchase Option) to acquire the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices that range from \$74.7 million at the end of the second year of the arrangement, increasing quarterly up to \$144.1 million at the fifth anniversary. 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, if not purchased through the exercise of the Purchase Option, will remain with SDI.

We have determined, pursuant to the guidance in FIN 46R, that SDI is a variable interest entity and we are its primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006.

At December 31, 2007, the investments held by SDI were \$31.6 million. The investments held by SDI in the consolidated balance sheet include the aggregate \$50.0 million of funding, less funds spent on the Development Programs as of the end of each reporting period.

At December 31, 2007, the noncontrolling interest balance was \$8.3 million. The noncontrolling interest in SDI in the consolidated balance sheet represents Symphony's equity investment in SDI of \$50.0 million, reduced by the \$5.6 million fair value of the warrants we issued and \$2.6 million of fees we paid to Symphony upon the transaction's closing, and the losses attributed to the noncontrolling interest in 2006 and 2007. The noncontrolling interest was further reduced when we recorded the \$15.0 million liability upon our exercise of the Program Option in April 2007, as that amount 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.

Net losses incurred by SDI and charged to the noncontrolling interest were \$8.7 million and \$9.7 million for the years ended December 31, 2007 and 2006, respectively. In accordance with FIN 46R, we have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated

statements of operations, and we will continue to deduct such losses until the carrying amount of the noncontrolling interest in the consolidated balance sheet is reduced to zero. We will be required to recognize losses incurred by SDI in our consolidated statements of operations after the noncontrolling interest balance has been exhausted.

9. Financing Agreement

In July 2007, Deerfield Management, a healthcare investment fund, and its affiliates (Deerfield) committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield’s commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loan principal for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, we have no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. Warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive warrants exercisable for the purchase of a total of 5,550,000 shares of the Company’s common stock, during the term of the loan agreement.

During the year ended December 31, 2007, we received from Deerfield \$5.5 million in cash which is recorded as a long-term liability in our consolidated balance sheet as of December 31, 2007. In addition, we issued to Deerfield warrants to purchase up to 3,550,000 shares of our common stock; such warrants were valued on the issuance date using the Black-Scholes valuation model. Total warrants issued in connection with the Deerfield financing agreement as of December 31, 2007 and their related assumptions under the Black-Scholes option valuation model are as follows (in thousands except for Black-Scholes Assumptions):

Warrant Issuance Date	Shares Issued	Black-Scholes Assumptions			Exercise Price per Share	Assigned Value Using Black-Scholes
		Risk-Free Interest Rate	Expected Life (In Years)	Volatility		
July 18, 2007	1,250	4.9%	5.5	0.7	\$ 5.13	\$ 3,350
October 18, 2007	1,300	4.2%	5.5	0.7	\$ 5.75	3,700
December 27, 2007	1,000	3.6%	5.5	0.7	\$ 5.65	2,746
Total	3,550					\$ 9,796

At the date of issuance, the warrant valuation is recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost will be amortized on a straight-line basis over the remaining term of the loan and recognized as interest expense in the statement of operations. For the fiscal year ended December 31, 2007, we amortized \$0.8 million of deferred transaction cost in interest expense. Additionally, for the fiscal year ended December 31, 2007 we recognized as interest expense \$0.8 million associated with the commitment fee of which \$0.4 million was paid on January 30, 2008.

10. Commitments and Contingencies

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated in September 2009 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been

included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2014. Total net rent expense related to our operating leases for the years ended December 31, 2007, 2006 and 2005, was \$2.1 million, \$1.8 million and \$1.4 million, respectively. Deferred rent was \$0.2 million as of December 31, 2007.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$25 thousand through 2007 and \$55 thousand annually thereafter until August 2010. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2007, excluding payments from the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2008	2,073
2009	2,452
2010	2,635
2011	2,693
Thereafter	12,743
Total	\$ 22,596

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of December 31, 2007 and December 31, 2006. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future upfront fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.6 million through 2012. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Such fees and milestone payments to the Regents could approximate \$1 million in 2008.

11. Collaborative Research, Development, and License Agreements

In October 2007, we entered into a global license and development collaboration agreement with Merck & Co., Inc. (Merck), to jointly develop HEPLISAV, a novel investigational hepatitis B vaccine. 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 a non-refundable 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 royalties on global sales of HEPLISAV. Revenue from the initial payment is deferred and recognized ratably over the contractual term of the collaboration agreement, which is estimated to be 13 years. For the year ended December 31, 2007, we recognized revenue of \$0.4 million related to the upfront fees. Collaboration revenue resulting from the performance of research and development services are recognized as related research and development costs are incurred, as provided for under the terms of these agreements. Cost reimbursement revenue under this collaboration agreement totaled \$5.8 million for the year ended December 31, 2007.

Also in October 2007, we entered into a manufacturing agreement with Merck for the supply of hepatitis B surface antigen. Under the terms of the agreement, 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. The October 2007 agreements with Merck are cancelable upon prior written notice to us, following which all rights and licenses to Merck with respect to HEPLISAV will terminate and revert to Dynavax.

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca AB, or AstraZeneca, for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration. The financial terms of the collaboration include an upfront fee of \$10 million plus research funding and preclinical milestones that could bring the total committed funding to \$27 million. The total potential deal value including future development milestones approximates \$136 million. Upon commercialization, we are also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$3.1 million for the year ended December 31, 2007. As of December 31, 2007, we recorded deferred revenue of \$10.5 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

In March 2005, we agreed to end our collaboration with UCB Farchim, S.A., or UCB, and regained full rights to our allergy program. During the second quarter of 2005, we received cash payments in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the collaboration. Collaboration revenue for the year ended December 31, 2005 included accelerated recognition of \$7.0 million in deferred revenue as we had no ongoing obligations under the collaboration. Collaboration revenue from UCB amounted to \$12.2 million during the year ended December 31, 2005.

In 2004, we were awarded \$0.5 million from the Alliance for Lupus Research to be received during 2006 and 2007 to fund research and development of new treatment approaches for lupus. We recognized revenue associated with the lupus grant of approximately \$0.1 million and \$0.2 million for the years ended December 31, 2007 and 2006, respectively.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the first quarter of 2008. In August 2007, we were awarded a two-year \$3.25 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with these grants is recognized as the related expenses are incurred. For years ended December 31, 2007, 2006 and 2005, we recognized revenue of approximately \$3.0 million, \$1.3 million and \$2.2 million, respectively.

12. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Years Ended December 31,		
	2007	2006	2005
Historical (in thousands, except per share amounts):			
Numerator:			
Net loss	\$ (59,971)	\$ (52,052)	\$ (20,555)
Denominator:			
Weighted-average common shares outstanding	39,746	32,340	25,915
Less: Weighted-average unvested common shares subject to repurchase	—	(1)	(1)
Denominator for basic and diluted net loss per share	39,746	32,339	25,914
Basic and diluted net loss per share	\$ (1.51)	\$ (1.61)	\$ (0.79)
Historical outstanding dilutive securities not included in diluted net loss per share calculation (in thousands):			
Options to purchase common stock	4,282	3,421	2,599
Warrants	5,550	2,084	84
	9,832	5,505	2,683

13. Stockholders' Equity

In the fourth quarter of 2005, we sold 5,720,000 shares of common stock in an underwritten public offering, raising net proceeds of approximately \$33.1 million. In the fourth quarter of 2006, we sold 7,130,000 shares of common stock in an underwritten public offering, raising net proceeds of approximately \$29.3 million. Also in the fourth quarter of 2006, we completed a draw down on an equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of common stock.

Stock Option Plans

As of December 31, 2007, we had three stock-based compensation plans: the 1997 Equity Incentive Plan; the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan.

In January 1997, we adopted the 1997 Equity Incentive Plan (the "1997 Plan"). The 1997 Plan provides for the granting of stock options to employees and non-employees of the Company. Options granted under the 1997 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted to employees, including directors who are also considered employees. NSOs may be granted to employees and non-employees. Options under the 1997 Plan may be granted for periods of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors, provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (ii) the exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. The options are exercisable immediately and generally vest over a four-year period (generally 25% after one year and in monthly ratable increments thereafter) for stock options issued to employees, directors and scientific advisors, and quarterly vesting over a four-year period or immediate vesting for stock options issued

to all other non-employees. All unvested shares issued under the 1997 Plan are subject to repurchase rights held by the Company under such conditions as agreed to by the Company and the optionee. The 1997 Plan expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

In January 2004, the Board of Directors and stockholders adopted the 2004 Stock Incentive Plan (the “2004 Plan”) which became effective on February 11, 2004. Subsequently, we discontinued granting stock options under the 1997 Plan. The exercise price of all incentive stock options granted under the 2004 Plan must be at least equal to 100% of the fair market value of the common stock on the date of grant. If, however, incentive stock options are granted to an employee who owns stock possessing more than 10% of the voting power of all classes of the Company’s stock or the stock of any parent or subsidiary of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value on the grant date and the maximum term of these incentive stock options must not exceed five years. The maximum term of an incentive stock option granted to any other participant must not exceed ten years.

As of December 31, 2007, 4,700,000 shares have been reserved and approved for issuance under the 2004 Plan, subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure.

Activity under our stock option plans is set forth below:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2006	1,997,141	3,421,339	\$ 5.26
Options authorized	400,000	—	—
Options granted	(1,137,085)	1,137,085	\$ 5.72
Options exercised	—	(5,666)	\$ 3.86
1997 Plan shares expired	(273,188)	—	—
Options cancelled:			
Options forfeited (unvested)	212,626	(212,626)	\$ 5.87
Options expired (vested)	57,677	(57,677)	\$ 4.88
Balance at December 31, 2007	<u>1,257,171</u>	<u>4,282,455</u>	\$ 5.36

Employee Stock Purchase Plan

In January 2004, the Board of Directors and stockholders adopted the 2004 Employee Stock Purchase Plan (the “Purchase Plan”). The Purchase Plan provides for the purchase of common stock by eligible employees and became effective on February 11, 2004. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the fifteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fourteenth day in February or August).

As of December 31, 2007, 496,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in our common stock or capital structure. To date, employees acquired 105,956 shares of our common stock under the Purchase Plan. At December 31, 2007, 390,044 shares of our common stock remained available for future purchases.

Stock-Based Compensation

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous

service). The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

	Employee Stock Options			Employee Stock Purchase Plan		
	2007	2006	2005	2007	2006	2005
Weighted-average fair value	\$ 3.53	\$ 4.04	\$ 3.68	\$ 1.96	\$ 2.28	\$ 3.03
Risk-free interest rate	4.7%	4.7%	3.7%	4.6%	4.9%	2.9%
Expected life (in years)	4.5	5.6	4	1.2	1.2	1.2
Volatility	0.8	0.8	0.7	0.7	0.7	0.7

Expected volatility is based on historical volatility of our stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were each found to have similar historical option exercise and termination behavior and thus were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

	Years Ended December 31,		
	2007	2006	2005
Employees and directors stock-based compensation expense	\$ 3,462	\$ 3,153	\$ 1,410
Non-employees stock-based compensation expense	69	130	(10)
Total	\$ 3,531	\$ 3,283	\$ 1,400

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized for the year ended December 31, 2007 was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of December 31, 2007, the total unrecognized compensation cost related to non-vested options granted amounted to \$6.8 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.6 years.

Total options exercised during the years ended December 31, 2007, 2006 and 2005 were 5,666, 411,985 and 140,825, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2007, 2006 and 2005 was approximately \$6 thousand, \$1.3 million and 0.8 million, respectively. No income tax benefits have been realized by us in 2007, 2006 and 2005, as we reported an operating loss in each year.

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of December 31, 2007:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding options (vested and expected to vest)	3,906,086	\$ 5.30	7.6	\$ 2,556
Options exercisable	1,910,407	\$ 4.68	6.5	\$ 2,321

Prior to January 1, 2006, we accounted for our stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees," or APB 25, and related interpretations, as permitted by FASB Statement No. 123, "Accounting for Stock-Based Compensation," or FAS 123. On January 1, 2006, we adopted the fair value recognition provisions of FAS 123R using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant

date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

As a result of the adoption of FAS 123R, we reduced our deferred stock compensation balance and additional paid in capital previously associated with APB 25 accounting by \$2.5 million as of January 1, 2006. Also as a result of adopting FAS 123R, our net loss for the year ended December 31, 2006 is higher by \$2.0 million, than if we had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share for the year ended December 31, 2006 are higher by \$0.06, than if we had continued to account for stock-based compensation under APB 25.

The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of FAS 123 to options granted under our stock-based compensation plans during the year ended December 31, 2005 (in thousands, except per share amounts). For purposes of this pro forma disclosure, the fair value of the options is estimated using the Black-Scholes option valuation model and amortized to expense on a straight-line basis over the vesting periods of the options.

	Year Ended December 31, 2005
Net loss, as reported	\$ (20,555)
Add: Stock-based employee compensation expense included in net loss	1,410
Less: Stock-based employee compensation expense determined under the fair value based method	(2,785)
Net loss, pro forma	\$ (21,930)
Net loss per share:	
Basic and diluted, as reported	\$ (0.79)
Basic and diluted, pro forma	\$ (0.84)

14. Employee Benefit Plan

Effective September 1997, we adopted the Dynavax Technologies Corporation 401(k) Plan (the "401(k) Plan"), which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. To date, we have not contributed to the 401(k) Plan.

15. Income Taxes

Loss including noncontrolling interest in Symphony Dynamo, Inc. before provision for income taxes on a worldwide basis consists of the following (in thousands):

	Years Ended December 31,		
	2007	2006	2005
U.S.	\$ (58,521)	\$ (59,862)	\$ (12,331)
Non U.S.	(1,450)	(1,933)	(8,224)
Total	\$ (59,971)	\$ (61,795)	\$ (20,555)

No income tax expense was recorded for the years ended December 31, 2007, 2006 and 2005 due to net operating losses in all jurisdictions. The difference between the income tax benefit and the amount computed by applying the federal statutory income tax rate to loss before income taxes is as follows (in thousands):

	2007	2006	2005
Income tax benefit at federal statutory rate	\$ (20,390)	\$ (21,045)	\$ (6,989)
State tax	(2,600)	(3,852)	(1,137)
Unbenefited foreign losses	—	(269)	4,752
Tax credits	(2,594)	(3,088)	(502)
Deferred compensation charges	495	(534)	342
In-process research and development	—	1,421	—
Change in valuation allowance	20,680	27,391	2,872
Change in foreign tax rates	1,966	—	—
Change in NOL	2,356	—	—
Other	87	(24)	662
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred tax assets and liabilities as of December 31, 2007 and 2006 consist of the following (in thousands):

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carry forwards	\$ 63,406	\$ 44,278
Research tax credit carry forwards	9,328	5,871
Accruals and reserves	7,067	1,697
Capitalized research costs	8,789	18,582
Other	2,279	277
	<u>90,869</u>	<u>70,705</u>
Less valuation allowance	(89,640)	(68,960)
Total deferred tax assets	<u>\$ 1,229</u>	<u>\$ 1,745</u>
Deferred tax liabilities:		
Other	—	—
Acquired intangible assets	(1,229)	(1,745)
Total deferred tax liabilities	<u>\$ (1,229)</u>	<u>\$ (1,745)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Management believes that, based on a number of factors, it is more likely than not that the deferred tax assets will not be realized. Accordingly, a full valuation allowance has been recorded for the net deferred tax assets at December 31, 2007 and 2006. The valuation allowance increased by \$20.7 million, \$31.2 million and \$2.9 million during the years ended December 31, 2007, 2006 and 2005, respectively. Approximately \$0.4 million of the valuation allowance for deferred tax assets relates to benefits of stock options deductions that when recognized, will be allocated directly to additional paid in capital.

A provision has not been made at December 31, 2007, for U.S. or additional foreign withholding taxes on undistributed earnings of the foreign subsidiary because it is the present intention of management to reinvest the undistributed earnings indefinitely in foreign operations. Currently there are no undistributed earnings in the foreign subsidiary as it has current and cumulative losses and thus no deferred tax liability would be necessary.

As of December 31, 2007, we had federal net operating loss carryforwards of approximately \$153.5 million and federal research and development tax credits of approximately \$5.5 million, which expire in the years 2011 through 2027. Of these net operating losses, approximately \$19.9 million are attributable to Symphony Dynamo, Inc., which expire in 2027.

As of December 31, 2007, we had net operating loss carryforwards for California state income tax purposes of approximately \$113 million, which expire in the years 2012 through 2026, and California state research and development tax credits of approximately \$5.7 million which do not expire.

As of December 31, 2007, we had net operating loss carryforwards for foreign income tax purposes of approximately \$17.0 million, which do not expire.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited. The adoption of FIN 48 had no impact on the reported carryforwards at December 31, 2007.

16. Selected Quarterly Financial Data (Unaudited; in thousands, except per share amounts)

	Year Ended December 31, 2007				Year Ended December 31, 2006			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenues	\$ 1,984	\$ 1,800	\$ 1,014	\$ 9,295	\$ 288	\$ 529	\$ 1,592	\$ 2,438
Net loss	\$ (13,090)	\$ (17,704)	\$ (17,101)	\$ (12,076)	\$ (8,172)	\$ (15,273)	\$ (12,152)	\$ (16,455)
Basic and diluted net loss per share	\$ (0.33)	\$ (0.45)	\$ (0.43)	\$ (0.30)	\$ (0.27)	\$ (0.50)	\$ (0.40)	\$ (0.44)
Weighted-average shares used in computing basic and diluted net loss per share(1)	39,727	39,741	39,753	39,765	30,487	30,560	30,605	37,645

(1) The weighted-average shares increased for fourth quarter of 2006 due to the follow on equity offerings that occurred in that period.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives.

Based on their evaluation as of the end of the period covered by this report, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2007. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an attestation report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

Attestation Report of Independent Registered Public Accounting Firm

To The Board of Directors and Stockholders
Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Dynavax Technologies Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Dynavax Technologies Corporation maintained in all material respects, effective internal control over financial reporting as of December 31, 2007 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2007 consolidated financial statements of Dynavax Technologies Corporation and our report dated March 13, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Francisco, California
March 13, 2008

(c) Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled “Proposal One — Elections of Directors,” “Executive Compensation,” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement in connection with the 2008 Annual Meeting of Stockholders (the “Proxy Statement”), which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2007.

We have adopted the Dynavax Code of Business Conduct and Ethics, a code of ethics that applies to our employees, including our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer, and to our non-employee directors. We will provide a written copy of the Dynavax Code of Business Conduct and Ethics to anyone without charge, upon request written to Dynavax, Attention: Deborah A. Smeltzer, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.

ITEM 11. EXECUTIVE COMPENSATION

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the section entitled “Security Ownership of Certain Beneficial Owners and Management” in the Proxy Statement. Information regarding our stockholder approved and non-approved equity compensation plans is incorporated by reference to the section entitled “Equity Compensation Plans” in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this Item is incorporated by reference to the sections entitled “Certain Relationships and Related Transactions” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

1. Financial Statements

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets
Consolidated Statements of Operations
Consolidated Statements of Stockholders’ Equity
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

2. Financial Statement Schedules

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

(b) Exhibits

Exhibit Number	Document
3.1(1)	Sixth Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(2)	Registration Rights Agreement.
4.2(2)	Form of Warrant.
4.3(3)	Form of Specimen Common Stock Certificate.
10.19(4)	2004 Non-employee Director Option Program (Revised) and 2005 Non-employee Director Cash Compensation Program, effective April 14, 2005 and amended February 23, 2006.
10.20(5)	Summary of Düsseldorf Lease Agreement as of August 14, 1990, as amended.
10.21(5)†	Definitive Commercial Agreement, dated April 21, 2006, among Dynavax Technologies Corporation, Rhein Biotech NV and Rhein Biotech GmbH.
10.22(5)†	Exclusive License Agreement, dated April 21, 2006, between Green Cross Vaccine Corp. and Rhein Biotech GmbH.
10.23(5)†	Share Sale and Purchase Agreement, dated March 27, 2006, between Dynavax Technologies Corporation and Rhein Biotech N.V.
10.24(5)†	License and Supply Agreement, dated February 28, 2002, between Corixa Corporation and Rhein Biotech N.V.
10.25(5)†	Purchase Option Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.26(5)†	Registration Rights Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.27(5)†	Warrant Purchase Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.28(5)†	Amended and Restated Research and Development Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.29(5)†	Novated and Restated Technology License Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.30(6)†	Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and Dynavax Technologies Corporation.
10.31(7)	Underwriting Agreement, dated October 3, 2006.
10.32 (8)†	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation.
10.33 (9)†	Loan Agreement, dated July 18, 2007, between Deerfield Private design Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Special Situations Fund International Limited and Deerfield Private Design International. L.P., and Dynavax Technologies Corporation.
10.34†	Merck Exclusive License and Development Collaboration Agreement, dated October 31, 2007.
10.35†	Merck Manufacturing Agreement, dated October 31, 2007.
21.1	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act. of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- (1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000-50577).
 - (2) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
 - (3) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.
 - (4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC.
 - (5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as filed with the SEC.
 - (6) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, as filed with the SEC.
 - (7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on October 4, 2006.
 - (8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC.
 - (9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, as filed with the SEC.
- † We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

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

Date: March 17, 2008

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

Date: March 17, 2008

Signature	Title	Date
<u>/s/ DINO DINA, M.D.</u> Dino Dina, M.D.	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 17, 2008
<u>/s/ DEBORAH A. SMELTZER</u> Deborah A. Smeltzer	Vice President, Operations and Chief Financial Officer <i>(Principal Financial Officer)</i>	March 17, 2008
<u>/s/ ARNOLD ORONSKY, Ph.D.</u> Arnold Oronsky, Ph.D.	Chairman of the Board	March 17, 2008
<u>/s/ NANCY L. BUC</u> Nancy L. Buc	Director	March 17, 2008
<u>/s/ DENNIS CARSON, M.D.</u> Dennis Carson, M.D.	Director	March 17, 2008
<u>/s/ DENISE M. GILBERT, Ph.D.</u> Denise M. Gilbert, Ph.D.	Director	March 17, 2008
<u>/s/ DAVID M. LAWRENCE, M.D.</u> David M. Lawrence, M.D.	Director	March 17, 2008
<u>/s/ PEGGY V. PHILLIPS</u> Peggy V. Phillips	Director	March 17, 2008
<u>/s/ STANLEY A. PLOTKIN, M.D.</u> Stanley A. Plotkin, M.D.	Director	March 17, 2008

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT 10.34

EXCLUSIVE LICENSE AND DEVELOPMENT COLLABORATION AGREEMENT
by and between
MERCK & CO., INC.
and
DYNAVAX TECHNOLOGIES CORPORATION

Execution

EXCLUSIVE LICENSE AND DEVELOPMENT COLLABORATION AGREEMENT

This Agreement (this "**Agreement**") is effective as of October 31, 2007 (the "**Effective Date**"), and is entered into by and between MERCK & CO., INC., a corporation organized and existing under the laws of New Jersey ("**Merck**"), and DYNAVAX TECHNOLOGIES CORPORATION, a corporation organized and existing under the laws of Delaware ("**Dynavax**").

RECITALS:

WHEREAS, Dynavax has developed Dynavax Know-How (as hereinafter defined) and has rights to Dynavax Patent Rights (as hereinafter defined);

WHEREAS, Merck and Dynavax desire to enter into a research collaboration to develop the Licensed Vaccine (as hereinafter defined) upon the terms and conditions set forth herein;

WHEREAS, Merck desires to obtain a license under the Dynavax Patent Rights and Dynavax Know-How, upon the terms and conditions set forth herein and Dynavax desires to grant such a license;

WHEREAS, Merck and Dynavax desire to enter into a separate Manufacturing Agreement (as hereinafter defined) as of the Effective Date with respect to furtherance of the collaboration under this Agreement;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency which are hereby acknowledged, Merck and Dynavax hereby agree as follows:

ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

1.1 "Act" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.

1.2 "Affiliate" shall mean (i) any corporation or business entity of which [*] of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by Merck or Dynavax; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds [*] (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of Merck or Dynavax; or (iii) any corporation or business entity of which [*] of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in

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(i) or (ii). Notwithstanding anything to the contrary in the foregoing, [*] shall not be considered an Affiliate of Merck.

1.3 **“Agreement”** shall have the meaning given such term in the preamble to this document.

1.4 **“BLA”** shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Application Authorization, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.5 **“Bridging Study”** shall mean the Clinical Trial conducted [*] as described in Schedule 2.1 as such study may be modified from time-to-time as part of the Development Plan in accordance with Section 2.4.3.

1.6 **“Calendar Quarter”** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7 **“Calendar Year”** shall mean each successive period of twelve (12) months commencing on “January 1 and ending on December 31.

1.8 **“Ceased Development Notice”** shall have the meaning given such term in Section 3.4.4.

1.9 **“Change of Control”** shall mean with respect to a Party: (1) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; (2) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

1.10 **“Clinical Product”** shall have the meaning given such term in Section 8.3.

1.11 **“Clinical Trial”** shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or post-approval Clinical Trial.

1.12 [*]

1.13 [*]

1.14 **“Combination Product”** shall mean a Product which includes [*]. All references to Product in this Agreement shall be deemed to include Combination Products.

1.15 **“Competing Pharma Change of Control”** shall mean a Change of Control in which a company or group of companies acting in concert (a) for whom aggregate worldwide sales of [*] in the Calendar Year that preceded the Change of Control were [*], or (b) [*].

1.16 **“Competitive Product”** shall mean a product [*] whether for sale by prescription, over-the-counter or any other method.

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- 1.17 “Control”, “Controls” or “Controlled by” shall mean with respect to any item of or right under Dynavax Patent Rights, Dynavax Know-How, Merck Know-How or any other intellectual property rights, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.
- 1.18 “Development Budget” shall have the meaning given such term in Section 2.3.
- 1.19 “Development Plan” shall have the meaning given such term in Section 2.1.
- 1.20 “Development Program” shall mean the research and development activities for Licensed Vaccine and Product undertaken by the Parties (or their respective Affiliate(s) and/or Third Parties who are acting on their behalf) as set forth in Article 2 and the Development Plan, which activities shall continue until [*].
- 1.21 “Dynavax” shall have the meaning given such term in the preamble to this Agreement.
- 1.22 [*]
- 1.23 “Dynavax IND” shall have the meaning given such term in Section 6.2.8.
- 1.24 “Dynavax Information and Inventions” shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Development Program or performance under this Agreement developed or invented solely by employees of Dynavax and/or its Affiliate(s) or other persons not employed by Merck or its Affiliate(s) who are acting on behalf of Dynavax and/or its Affiliates.
- 1.25 “Dynavax Know-How” shall mean all information and materials, including but not limited to, discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation Dynavax Information and Inventions and Dynavax’s rights in Joint Information and Inventions), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement (i) are Controlled by Dynavax and/or its Affiliate(s), (ii) are not generally known and (iii) are necessary or useful to Merck in connection with the Development Program or the research, development, manufacture, marketing, use or sale of Licensed Vaccine or Product in the Territory; excluding, however, any Merck Know-How.
- 1.26 “Dynavax Patent Rights” shall mean any and all patents and patent applications in the Territory (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention) which during the term of this Agreement are Controlled by Dynavax and/or its Affiliate(s), including but not limited to those listed on Schedule 1.26, which: (i) claim or cover Licensed Vaccine and/or Product, including without limitation any improvements thereto; or (ii) claim or cover Dynavax Information and Inventions or Joint Information and Inventions; or (iii) are divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the likes of any such patents and patent applications and foreign equivalents of the foregoing.

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- 1.27 **“Effective Date”** shall have the meaning given such term in the preamble to this Agreement.
- 1.28 **“European Market”** shall mean any one of [*].
- 1.29 **“Field”** shall mean [*].
- 1.30 **“Filing of a BLA”** shall mean the acceptance by a Regulatory Authority of a BLA for filing.
- 1.31 **“First Commercial Sale”** shall mean the first sale for end use or consumption of Product in a country, excluding, however, any sale or other distribution for use in a Clinical Trial or “compassionate use” sales.
- 1.32 **“Full Time Equivalent”** or **“FTE”** shall mean the equivalent of a full-time employee’s work time over a twelve-month period (including normal vacations, sick days and holidays); provided that a FTE shall not include [*]. The portion of an FTE year devoted by an employee to the Development Program shall be determined by dividing the number of full days during any twelve-month period devoted by such employee to the Development Program by [*] days during such twelve-month period.
- 1.33 **“FTE Rate”** shall mean the amount Merck will pay Dynavax over a consecutive twelve (12) month period during the Development Program to support one (1) Dynavax FTE dedicated to the Development Program. [*].
- 1.34 **“GLP”** or **“Good Laboratory Practice”** shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.
- 1.35 **“Hep B Field”** shall mean [*].
- 1.36 **“Hepatitis B Surface Antigen”** shall mean [*].
- 1.37 **“IND”** shall mean an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.38 **“Information”** shall mean any and all information and data, including without limitation all Merck Know-How, all Dynavax Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party and/or its Affiliate(s) to the other Party and/or its Affiliate(s) in connection with this Agreement.
- 1.39 **“Invention”** shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice as a result of the Development Program.

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- 1.40 **“Joint Development Committee” or “JDC”** shall mean the joint development committee established to facilitate the Development Program as more fully described in Section 2.4.
- 1.41 **“Joint Development Team” or “JDT”** shall have the meaning given such term in Section 2.4.5.
- 1.42 **“Joint Information and Inventions”** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Development Program developed or invented jointly by employees of Merck, its Affiliates and/or a Third Party acting on behalf of Merck and/or its Affiliates, on the one hand, and Dynavax, its Affiliates and/or a Third Party acting on behalf of Dynavax and/or its Affiliates, on the other hand.
- 1.43 **“Licensed Vaccine”** shall mean [*] preparation that contains both the Hepatitis B Surface Antigen and 1018 ISS for [*].
- 1.44 **“Manufacturing Agreement”** shall mean the Manufacturing Agreement, effective as of the Effective Date, by and between Merck and Dynavax, as such agreement may be amended, restated or otherwise modified from time to time.
- 1.45 **“Marketing Authorization”** shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in any country (including without limitation all applicable pricing and governmental reimbursement approvals even if not legally required to sell Product in a country).
- 1.46 **“Merck”** shall have the meaning given such term in the preamble to this Agreement.
- 1.47 **“Merck Information and Inventions”** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the Development Program developed or invented solely by employees of Merck and/or its Affiliate(s), or other persons not employed by Dynavax and/or its Affiliate(s) who are acting on behalf of Merck and/or its Affiliate(s).
- 1.48 **“Merck Know-How”** shall mean any information and materials, including but not limited to, discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation Merck’s Information and Inventions and Merck’s rights in Joint Information and Inventions), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement, (i) are Controlled by Merck and/or its Affiliate(s), (ii) are not generally known and (iii) are in Merck’s reasonable opinion necessary to Dynavax in the performance of its obligations under the Development Program and Manufacturing Agreement.
- 1.49 **“Net Sales”** shall mean [*].
- 1.50 **“Not Incurred Expense Period”** shall have the meaning given such term in Section 2.3.1.
- 1.51 **“Not Incurred Prior Development Expenses”** shall have the meaning given such term in Section 2.3.1.
- 1.52 **“Party”** shall mean Merck or Dynavax, individually, and **“Parties”** shall mean Merck and Dynavax, collectively.

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- 1.53 **“Phase I Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- 1.54 **“Phase II Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- 1.55 **“Phase III Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.56 **“Potential Future Sublicensed Technology”** shall have the meaning given such term in Section 3.5.1.
- 1.57 **“Product(s)”** shall mean [*] preparation in final form containing Licensed Vaccine, (i) for sale by prescription, over-the-counter or any other method; or (ii) for administration to human patients in a Clinical Trial, for any and all uses in the Field, including without limitation any Combination Product.
- 1.58 **“Project Leader”** shall have the meaning given such term in Section 2.4.6.
- 1.59 **“Regulatory Authority”** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.
- 1.60 **“Related Party”** shall mean each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable. Notwithstanding anything to the contrary in the foregoing and for the purposes of clarity, [*] shall be a Related Party in the event [*].
- 1.61 [*]
- 1.62 [*]
- 1.63 **“Territory”** shall mean all of the countries in the world, and their territories and possessions.
- 1.64 **“Third Party”** shall mean an entity other than Merck and its Related Parties, and Dynavax and its Affiliates.
- 1.65 **“Wind Down Activities”** shall have the meaning given such term in Section 10.4.3(f).
- 1.66 **“Wind Down Period”** shall have the meaning given such term in Section 10.4.3(f).
- 1.67 **“1018 ISS”** shall mean the adjuvant commonly identified within Dynavax as 1018 ISS, an immunostimulatory sequence (ISS) composed of the [*].

ARTICLE 2 RESEARCH PROGRAM

2.1 **General.** Merck shall have sole responsibility for the development of Licensed Vaccine and Products in the Field in the Territory within the scope of the rights granted to Merck under this

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Agreement, subject to Dynavax's performance of its development obligations as set forth in this Article 2, its manufacturing and supply, and technology transfer obligations set forth in Article 8, and its other obligations set forth in this Agreement and the Manufacturing Agreement. Development Program activities shall be conducted in accordance with the development plan (the "**Development Plan**"), as it may be amended or otherwise modified from time-to-time by the JDC in accordance with Section 2.4, or otherwise upon mutual written agreement between the Parties. An initial general description of the various activities to be undertaken as part of the Development Plan is set forth in Schedule 2.1 attached hereto. The Development Program and the Development Plan shall cover the period from the Effective Date until such time as [*]. Without limiting the foregoing, the Development Plan, once comprehensively designed by the JDC in accordance with Section 2.4.5, shall outline which Party is responsible for conducting particular Development Program activities, and an outline of the major activities, goals and timelines for Licensed Vaccine and Product development, which may include, without limitation, activities with respect to [*]. For the purposes of clarity, the Development Plan shall not include the foregoing activities with respect to [*].

2.2 Conduct of Development. Dynavax and Merck each shall use commercially reasonable efforts to complete promptly the work assigned to it for the Development Program by using their respective good faith efforts to allocate sufficient time, effort, equipment and facilities to the Development Program and to use personnel, employees and agents with sufficient skills and experience as are required to accomplish the Development Program, in each case in accordance with the terms of this Agreement and the Development Plan. Without limiting any other provision of this Agreement, neither Dynavax nor its Affiliates shall perform development or other research work on the Licensed Vaccine or Product except in accordance with the Development Plan or otherwise with the prior written consent of Merck.

Dynavax and Merck each shall conduct the Development Program in compliance with all applicable laws, rules and regulations, including, without limitation, Good Laboratory Practice. In addition, if animals are used in research hereunder, each Party will comply with the Animal Welfare Act or any other applicable local, state, national and international laws and regulations relating to the care and use of laboratory animals. Merck encourages Dynavax to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Any animals which are used in the course of the Development Program, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes. Each Party shall notify the other Party in writing of any material deviations from applicable regulatory or legal requirements. Each Party hereby certifies to the other that it has not employed, and will not employ or otherwise use in any capacity, the services of any person debarred under United States law, including but not limited to Section 21 USC 335a, in performing any portion of the Development Program.

Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Development Program activities. Dynavax shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Development Program activities only as specifically set forth in the Development Plan or upon Merck's prior written consent, which consent shall not be unreasonably withheld. The Parties agree that Rhein Biotech GmbH (also identified as Dynavax Europe) shall be considered an approved Affiliate under this Agreement so long as it remains an Affiliate of Dynavax. Notwithstanding any such consent, both Parties shall remain at all times

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fully liable for its respective responsibilities under the Development Program. Each Party shall ensure by written agreement that its Affiliates, and their personnel, employees, and agents and Third Parties performing activities under the Development Program on such Party's behalf comply with confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in Article 4. Dynavax shall further ensure by written agreement that its Affiliates and Third Parties performing activities under the Development Program on Dynavax's behalf are obligated to assign any rights they may have in any Dynavax Information and Inventions or Joint Information and Inventions arising as a result of such work to Dynavax.

2.3 Development Program Funding.

2.3.1 **Merck Funding Responsibility.** Merck shall be responsible for its own costs under the Development Program, and shall reimburse Dynavax for the costs of Dynavax's activities under the Development Program in accordance with this Section 2.3. Subject to the Development Budget process outlined below, Merck shall reimburse Dynavax for activities performed by Dynavax and, as permitted in accordance with Section 2.2, its Affiliates and Third Parties under the Development Plan [*]. Unless otherwise agreed in writing, Merck shall have no obligation to reimburse Dynavax for any of Dynavax's Development Plan expenses other than as specified above, including without limitation for any [*]. Except as expressly provided in Section 5.2.2, Merck shall have no obligation to reimburse Dynavax for (A) any development activities conducted by, or on behalf of, Dynavax prior to the Effective Date, or (B) any activities not specified in the Development Plan and the Development Budget unless otherwise approved pursuant to Section 2.4.1; provided that with respect to clause (A) above, the Parties acknowledge that Dynavax has accrued but not yet incurred all of its costs for certain periods prior to the Effective Date and the Parties therefore agree that Merck shall reimburse Dynavax for its development costs for its efforts to develop the Licensed Vaccine only covering the period from September 1, 2007 through the Effective Date (the "**Not Incurred Expense Period**") consistent with the reimbursement principals specified in the second sentence of this Section 2.3.1 and at an amount not to exceed the amount budgeted for the Not Incurred Expense Period as specified in Schedule 2.3 attached hereto (such development costs during the Not Incurred Expense Period being referred to herein as the "**Not Incurred Prior Development Expenses**"). Dynavax shall apply all development funding it receives from Merck under this Section 2.3 solely to carry out its development activities in accordance with the Development Plan, the Development Budget and the terms and conditions of this Agreement. Notwithstanding anything to the contrary in this Section 2.3, any Merck obligation to compensate Dynavax for its manufacturing and supply of any Clinical Product and commercial supply shall be as specified in Article 8 and the Manufacturing Agreement.

2.3.2 **Development Budget.**

- (a) The JDC shall establish a budget (the "**Development Budget**") which shall cover all activities required by the Development Plan, and shall specifically identify those activities that are to be carried out by, or on behalf of Dynavax and the estimated FTE costs and out of pocket costs for such Dynavax activities. The Development Budget for the current and the following Calendar Year shall be

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specified in a level of detail consistent with Merck's standard practices for such reports, which practices shall be identified to Dynavax by Merck from time to time hereunder. An initial development budget has been attached as Schedule 2.3 hereto and it is understood that any amounts specified therein for the 2007 Calendar Year are to be adjusted as appropriate to account for the amounts paid to Dynavax by Merck under Section 5.2.2 for the period from January 1, 2007 through August 31, 2007 and any amounts paid by Merck to Dynavax for the Not Incurred Expense Period.

- (b) The JDC shall review, monitor and propose revisions the Development Budget on a periodic basis. To assist the JDC and Merck in establishing and revising the Development Budget, upon the request of the JDC or Merck from time-to-time, Dynavax shall provide Merck with estimates of its costs for activities assigned to Dynavax under the Development Plan for any subsequent Calendar Quarter(s) an/or Calendar Year(s). Unless specified in Schedule 2.3 or previously agreed to by Dynavax as part of a JDC approved Development Budget, Dynavax shall not be obligated to perform any activities under the Development Plan if it in good faith believes that the estimated costs specified in the then current Development Budget for such activities are not sufficient.

2.3.3 **Invoicing for Dynavax Development Activities.** Promptly and in any event no later than [*] following the conclusion of each Calendar Quarter, in which Dynavax has performed work under the Development Plan, Dynavax shall provide Merck with a detailed invoice covering such Calendar Quarter including a detailed list of the work actually performed by or on behalf of Dynavax under the Development Plan for such Calendar Quarter, together with an accounting of Dynavax and its Affiliate's FTE efforts and its out of pocket costs for such work; provided that (a) within [*] after the Effective Date, Dynavax may provide Merck with an invoice for Not Incurred Prior Development Expenses that cover development work performed by Dynavax during the month of September 2007; and (b) the invoice for the first Calendar Quarter to conclude after the Effective Date shall include Not Incurred Prior Development Expenses during the Not Incurred Expense Period to the extent not already included in an invoice provided by Dynavax in accordance with clause (a) above. Merck shall pay Dynavax within [*] of Merck's receipt of a reasonably detailed invoice. If Dynavax becomes aware, or in good faith believes, that its costs for any particular Development Plan activity assigned to it will exceed the amount set forth in the Development Budget therefor, it shall obtain prior approval from the JDC for any such variance. Notwithstanding anything to the contrary in this Agreement, unless otherwise agreed to by the JDC or the Parties, Merck's total financial obligations for work performed by Dynavax under the Development Program for any Calendar Quarter shall not exceed the amount set forth in the Development Budget therefor.

2.3.4 **Informal Monitoring of Dynavax Costs.** On a periodic basis (to be agreed by the Parties) during each Calendar Quarter in which Dynavax is performing work under the Development Plan, and as otherwise requested by Merck from time-to-time, on an informal basis the Program Coordinators for each Party shall discuss Dynavax's progress based on Dynavax's then current internal records and forecasts, including a break down of Dynavax FTE efforts and its out of pocket costs expended and projected for work

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assigned to Dynavax under the Development Plan for such Calendar Quarter. The goal of such discussions shall be to ensure that the contemplated Dynavax activities under the Development Plan are appropriately completed and performed within the Development Budget therefor.

- 2.3.5 **Merck Audit Rights.** Dynavax will keep (and cause its Affiliates and agents performing services on its behalf under the Development Program to keep) true, accurate and complete records of its work efforts on an FTE basis and its out of pocket costs in sufficient detail to permit determination of the costs of such services consistent with Section 2.3.1, and will provide Merck's Program Coordinator with reasonable evidence of such costs to enable Merck's Program Coordinator to monitor and report on such expenses as compared to the Development Budget. In addition, upon the written request of Merck providing at least [*] notice and not more than [*] in each Calendar Year, Dynavax will permit Merck or its independent certified accountants of nationally and/or regionally recognized reputation, to have access during ordinary business hours to such of Dynavax records (and shall cause its Affiliates, and agents to permit such access to their records) as may be necessary to substantiate the accuracy of any of Dynavax's invoices provided to Merck and the conformance of such invoices to the Development Budget. The audit of the expenses for a calendar year must occur within [*] of the end of a Calendar Year. If there is a dispute between Merck and Dynavax concerning the accuracy of any Dynavax invoice for its work under the Development Program, such dispute shall first be submitted to the JDC for resolution and if the JDC is unable to resolve such dispute, the Parties shall meet and in good faith attempt to resolve such dispute between the Executive Officers (as defined in Section 2.4.1), and if such dispute remains, either Party may submit the dispute to the dispute resolution process set forth in Section 12.6.

2.4 Joint Development Committee. The Parties hereby establish a committee to facilitate the Development Program as follows:

- 2.4.1 **Composition of the Joint Development Committee.** The Development Program shall be conducted under the direction of a joint development committee (the "**Joint Development Committee**" or "**JDC**") comprised of [*] Merck representatives of Merck and [*] representatives of Dynavax. The Parties shall identify their representative to the JDC within [*] after the Effective Date. Each Party may change its representatives to the JDC from time to time in its sole discretion, effective upon written notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Development Program. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JDC meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 4.1. The JDC shall be chaired by a representative of Merck. Decisions of the JDC shall be made unanimously by the representatives. In the event that the JDC cannot or does not, after good faith efforts, reach agreement on an issue, the resolution and/or course of conduct shall be determined by [*]; provided, however, if such dispute relates to [*], the JDC (or either Party's members thereof) may refer such dispute to a discussion (to be held within [*], or such other period as mutually agreed) by a vice president responsible for clinical research for Merck and the Chief Executive Officer of

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Dynavax, or their designees (the “**Executive Officers**”); provided further if the Executive Officers are unable to resolve the dispute after good faith discussion, the resolution and/or course of conduct shall be determined by [*]. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.

- 2.4.2 **Meetings.** The JDC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, alternating between Dynavax and Merck facilities (or such other location may be determined by the JDC). Alternatively, the JDC may meet by means of teleconference, videoconference or other similar communications equipment.
- 2.4.3 **Minutes.** The JDC shall assign a member to have the responsibility for preparing definitive minutes of each JDC meeting, a draft of which shall be circulated for comment to all members of the JDC within [*] after the relevant JDC meeting. Such minutes shall provide a description, in reasonable detail, of the discussions held at the meeting, a list of any actions or determination approved by the JDC and any disagreements or other matters not resolved by the JDC at such meeting. The members shall provide comments within [*] of receipt of the draft minutes. The Project Leaders for the Parties shall discuss any comments on such minutes and finalize the minutes by no later than [*] after the relevant meeting.
- 2.4.4 **Scope of JDC responsibilities.** The JDC shall have the following responsibilities: [*].

Notwithstanding anything to the contrary in this Article 2, [*]; provided, however, thereafter upon reasonable notice Merck may call a meeting of the JDC from time-to-time to discuss and exchange information regarding the Products and any other scientific and development information relating to the work performed during the Development Program and to address additional development support to be provided by Dynavax in accordance with the following paragraph.

In addition, upon Merck’s request, on terms and conditions to be mutually agreed in good faith between the Parties, Dynavax shall provide reasonable assistance and support to Merck after the Development Program has terminated, as needed [*]. Failure to agree on terms negotiated in good faith shall not be deemed a breach of this Agreement by either Party.

2.4.5 **Joint Development Team.**

- (a) The JDC shall establish a working group (the “**Joint Development Team**” or the “**JDT**”) whose first priority after the Effective Date shall be [*]. Subject to approval and oversight of the JDC, the JDT shall have the day-to-day responsibility to implement the Development Program in accordance with the Development Plan and to propose amendments to the Development Plan for consideration by the JDC. The JDT shall also be responsible for forecasting requirements for clinical supplies of Licensed Vaccine and Product. The composition of the JDT shall include [*], and the composition may change from time to time as determined by the JDC as appropriate to the stage of development and the functional capabilities of the Parties. The JDT shall operate consistent

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with Merck's procedures as they would apply to an internal Merck program at an equivalent stage of development having a similar commercial value.

- (b) The Project Leaders shall be responsible for scheduling JDT meetings, preparing agendas and sending out notices of JDT meetings and agendas therefor. The JDT meetings may be held telephonically, by video-conference or in person at the appropriate Merck facility or such other location established by the JDT or agreed to by the Parties.
- (c) All strategic and operational activities of the JDT, including without limitation, approval of, and modification to, the Development Plan and Development Budget, shall be subject to the oversight and approval of the JDC in accordance with Section 2.4.3.

2.4.6 **Project Leaders.** Merck and Dynavax each shall appoint a person (a "**Project Leader**") to coordinate its part of the Development Program and the activities of the JDT. The Project Leaders shall be the primary contact between the Parties with respect to the Development Program. Each Party shall notify the other within [*] of the Effective Date of the appointment of its Project Leader and shall notify the other Party as soon as practicable upon changing this appointment.

2.5 **Exchange of Information.** Upon execution of this Agreement, and on a regular basis during the term of the Agreement, Dynavax shall disclose to Merck in English and in writing or in an electronic format all Dynavax Know-How not previously disclosed. Without limiting the foregoing, as requested by Merck after the Effective Date, Dynavax shall provide to Merck all preclinical data, clinical samples, data with respect to drug development activities, including without limitation analytical test method development and stability testing, toxicology, formulation, quality assurance/quality control development, manufacturing, and chemistry, or clinical data relating to Dynavax's development activities for Licensed Vaccines and/or Product in Dynavax's possession or control that are necessary or useful for Licensed Vaccine and/or Product regulatory filings worldwide. Merck shall promptly disclose to Dynavax during the term of the Development Program all Merck Know-How.

2.6 **Records and Reports.**

2.6.1 **Records.** Dynavax shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Development Program by Dynavax.

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- 2.6.2 **Copies and Inspection of Records.** Merck shall have the right, during normal business hours and upon reasonable notice, to inspect all such records of Dynavax referred to in Section 2.6.1. Merck shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employees and/or consultants involved in the activities contemplated hereunder to visit the offices and laboratories of Dynavax, its Affiliates and any of its Third Party contractors as permitted under Section 2.2 during normal business hours and upon reasonable notice, and to discuss the Development Program work and its results in detail with the technical personnel and consultants of Dynavax. Upon request, Dynavax shall provide copies of the records described in Section 2.6.1.
- 2.6.3 **Quarterly Reports.** Within [*] following the end of each Calendar Quarter during the Development Program and more frequently as specified in the Development Plan, Dynavax shall provide to Merck a written progress report in English which shall describe the work performed to date on the Development Program, evaluate the work performed in relation to the goals of the Development Program and provide such other information required by the Development Program or reasonably requested by Merck relating to the progress of the goals or performance of the Development Program.

2.7 Research Information and Inventions. The entire right, title and interest in:

- 2.7.1 Dynavax Information and Inventions shall be owned solely by Dynavax;
- 2.7.2 Merck Information and Inventions shall be owned solely by Merck; and
- 2.7.3 Joint Information and Inventions shall be owned jointly by Dynavax and Merck. Subject to the licenses granted under this Agreement to Merck, Merck and Dynavax will each have an equal undivided share in the Joint Information and Inventions, without obligation to account to the other for exploitation thereof, or to seek consent of the other Party for the grant of any license thereunder.

Dynavax shall promptly disclose to Merck in writing the development, making, conception or reduction to practice of Dynavax Information and Inventions. Each Party shall promptly disclose to the other Party in writing the development, making, conception or reduction to practice of Joint Information and Inventions.

2.8 Materials. In order to facilitate the Development Program, each Party shall provide the other Party with sufficient quantities of material as set forth in Development Plan and other materials as each such Party may provide from time to time under this Agreement (the "**Materials**"). Each Party shall use the Materials supplied by the other Party under the Development Program solely for the purposes of carrying out its respective activities under the Development Program in accordance with the terms of this Agreement and, consistent with the licenses granted to either Party under this Agreement. Neither Party shall transfer, deliver or disclose any such Materials of the other Party, or any derivatives, analogs, modifications or components thereof, to any Third Party without the prior written approval of the providing Party, except that Merck may transfer Materials provided by Dynavax (and/or any derivatives, analogs, modifications or components thereof) without Dynavax's prior written consent to Related Parties, agents and subcontractors, and to Regulatory Authorities for the purpose of carrying out the development and

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commercialization of Licensed Vaccine and Product. The Materials supplied by Merck are not to be used in humans, except as contemplated by this Agreement and permitted by applicable law and shall not be transferred, delivered or disclosed to any Third Party by Dynavax without the prior written approval of Merck. Any unused Materials supplied by a Party hereunder and any derivatives, analogs, modifications or components thereof shall be, at the receiving Party's option, either returned to or destroyed in accordance with instructions by the Party providing the Materials.

2.9 Use of Human Materials. If any human cell lines, tissue, human clinical isolates or similar human-derived materials ("**Human Materials**") have been or are to be collected and/or used in the Development Program by a Party, such Party represents and warrants (i) that it has complied, or shall comply, with all applicable laws, guidelines and regulations relating to the collection and/or use of the Human Materials and (ii) that it has obtained, or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. The Party using the Human Materials shall provide documentation of such approvals and consents upon the other Party's request. Each Party further represents and warrants that to its knowledge such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities ("**Providers**") who contributed the Human Materials, including, without limitation, any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purposes.

ARTICLE 3 LICENSE; EXCHANGE OF INFORMATION; DEVELOPMENT AND COMMERCIALIZATION; CERTAIN SUBLICENSE OBLIGATIONS.

3.1 License Grants.

3.1.1 Grants to Merck.

- (a) Subject to the terms and conditions of this Agreement, Dynavax hereby grants to Merck an exclusive (even as to Dynavax) license in the Territory under Dynavax Patent Rights and Dynavax Know-How with a right to sublicense, to use, offer to sell, sell or import the Licensed Vaccine and/or the Product(s) for any and all uses in the Field.
- (b) Subject to the terms and conditions of this Agreement, Dynavax hereby grants to Merck an exclusive (even as to Dynavax) license under Dynavax Patent Rights and Dynavax Know-How with a right to sublicense, to make and have made the Licensed Vaccine and/or the Product(s) in the Territory other than the United States, for any and all uses in the Territory in the Field within the license scope specified under 3.1.1(a).
- (c) Subject to the terms and conditions of this Agreement, Dynavax hereby grants to Merck a non-exclusive license under Dynavax Patent Rights and Dynavax Know-How with a right to sublicense, to make and have made the Licensed Vaccine and/or the Product(s) in the United States, for any and all uses in the Territory in the Field within the license scope specified under 3.1.1(a).

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- 3.1.2 Grants to Dynavax. Subject to the terms and conditions of this Agreement, Merck hereby grants to Dynavax a non-exclusive, non-sub-licensable (except to the extent Dynavax is permitted to use its Affiliate(s) or Third Parties in performing its obligations under the Development Program in accordance with Section 2.2) license under Merck Know-How to the extent necessary for Dynavax to perform its obligations under the Development Program in accordance with Article 2 and its regulatory obligations in accordance with Article 9.
- 3.1.3 Dynavax Retained Rights. Within the scope of the licenses granted to Merck under Section 3.1.1, Dynavax shall retain rights under the Dynavax Patent Rights and Dynavax Know-How solely as necessary for Dynavax to perform its obligations under this Agreement and the Supply Agreement, including its obligation under the Development Program in accordance with Article 2; and its obligations to manufacture and supply Clinical Product and commercial supply to Merck and its Related Parties in accordance with Article 8 and the Manufacturing Agreement. Dynavax further agrees that it shall not use or permit its Affiliates or Third Parties to use (directly or indirectly whether through a license or otherwise) Dynavax Patent Rights or Dynavax Know-How to develop, use, make, have made, offer to sell, sell or import Licensed Vaccines or Products in the Field within the Territory other than to perform its obligations under this Agreement and the Manufacturing Agreement.
- 3.2 **Non-Exclusive License Grant**. In the event that the making, having made, use, offer for sale, sale or import by Merck, or its Related Parties, of Licensed Vaccine or Products would infringe during the term of this Agreement a claim of issued letters patent which Dynavax owns (or, as of the Effective Date has the rights to license) and which patents are not covered by the grant in Section 3.1.1, Dynavax hereby grants to Merck, to the extent Dynavax is legally able to do so and subject to Section 3.5.1, a non-exclusive, sublicensable, royalty-free license in the Territory under such issued letters patent for Merck and its Related Parties to develop, make, have made, use, sell, offer for sale or import Licensed Vaccine(s) and Product(s) in the Territory.
- 3.3 **No Implied Licenses**. Except as set forth in Sections 3.1 and 3.2, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any patents or patent applications owned or controlled by the other Party or its Affiliates. In furtherance of the foregoing except as expressly provided under this Agreement and the Manufacturing Agreement, Dynavax acknowledges and agrees that Merck is not granting to Dynavax any rights under Merck Know-How to make, have made, use, offer to sell, sell or import the Licensed Vaccine, or any component thereof, including without limitation, the Hep B Surface Antigen, on behalf of Dynavax itself, its Affiliates or any Third Party other than to perform Dynavax's obligations under this Agreement and the Manufacturing Agreement on behalf of Merck.

3.4 **Diligence and Progress Reports**.

- 3.4.1 Development and Commercialization. Merck shall use commercially reasonable efforts, consistent with the usual practice followed by Merck in pursuing the commercialization and marketing of its other vaccine products of a similar commercial value, at its own expense, to develop and commercialize a Product in such countries in the Territory where in Merck's reasonable opinion it is commercially viable to do so.

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- 3.4.2 Development Progress Reports. During the Development Program, Dynavax will be informed as to the development status of the Licensed Vaccine and the Product through its participation in the JDC and the fulfillment of its obligations under the Development Plan. [*].
- 3.4.3 Commercialization Reports. In addition, commencing [*] for Product in the Territory. Such meetings shall be held in person or by videoconference or other means mutually agreed upon and at a time consistent with the business and profit planning cycles of Merck for Product.
- 3.4.4 Ceased Development Notice. Merck shall promptly notify Dynavax (such notice being a “**Ceased Development Notice**”) within [*] in the event that [*]. Following receipt of a Ceased Development Notice, Dynavax shall have a right to terminate this Agreement in accordance with Section 10.2.2.
- 3.4.5 Confidentiality. For the purposes of clarity, all Information provided by Merck or its Affiliates under this Section 3.4 shall remain subject to the confidentiality and non-use obligations of Dynavax in accordance with Article 4 and, without limiting the foregoing, Dynavax shall not use any such Information for purposes that might reasonably be expected to compete with Licensed Vaccine and Product.
- 3.4.6 Excused Performance. Subject to Merck’s obligation under Section 3.4.4 and Dynavax’s resulting rights under Section 10.2.2, the obligation of Merck with respect to Product under Section 3.4.1 are expressly conditioned upon the continuing absence of any significant adverse condition or event relating to the safety or efficacy of the Product, [*], and the obligation of Merck to develop or market any such Product shall be delayed or suspended so long as in Merck’s opinion any such condition or event exists and Merck is diligently seeking to resolve such condition or event.

3.5 Third Party Technology.

- 3.5.1 [*]
- 3.5.2 Other Third Party Technology. Dynavax shall be responsible for all consideration payable under any agreement between Dynavax and a Third Party under which Dynavax has been granted a license or otherwise obtains rights in such Third Party’s intellectual property (other than as expressly provided in Section **Error! Reference source not found.** with respect to the [*]) as follows:
- (a) After the Effective Date, Dynavax shall provide Merck with prior notice if Dynavax intends to negotiate an agreement with any Third Party under which Dynavax will be granted a license to, or will otherwise obtain rights in, a Third Party’s intellectual property (whether or not patented or patentable) that with respect to the Licensed Vaccine and/or Product would be sublicensed, in whole or in part, to Merck under the licenses granted by Dynavax to Merck under Section 3.1.1 (each a “**Potential Future Sublicensed Technology**”), and Dynavax shall keep Merck advised of the status of such negotiations;

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- (b) If Merck desires to obtain rights to such Potential Sublicensed Technology under a sublicense from Dynavax pursuant to Section 3.1.1: (i) Merck shall promptly so notify Dynavax and thereafter the Parties shall discuss, in good faith, on the terms and conditions under which such Potential Future Sublicensed Technology shall be obtained with respect to the Licensed Vaccine and/or Product and Dynavax shall use commercially reasonable efforts to secure a license that is sublicensable to Merck on the same terms and conditions applicable to Dynavax thereunder, (ii) if Dynavax is successful in obtaining such Potential Future Sublicensed Technology, the Parties shall in good faith negotiate [*], and (iii) such Potential Future Sublicensed Technology shall be within the scope of the rights licensed by Dynavax to Merck under Section 3.1.1; and
- (c) If Merck does not desire to obtain sublicensed rights to such Potential Sublicensed Technology under Section 3.1.1 Merck shall so notify Dynavax, and if Dynavax is successful in obtaining such Potential Future Sublicensed Technology, such Potential Future Sublicensed Technology shall be excluded from the rights licensed by Dynavax to Merck under Section 3.1.1 and Merck shall have no responsibility to reimburse Dynavax for any cost related thereto.

ARTICLE 4 CONFIDENTIALITY AND PUBLICATION.

4.1 Nondisclosure Obligation. All Information disclosed by one Party and/or its Affiliate(s) (the “**Disclosing Party**”) to the other Party and/or its Affiliate(s) (the “**Receiving Party**”) under this Agreement shall be maintained in confidence by the Receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the Disclosing Party, except to the extent that such Information:

- 4.1.1 is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party’s business records;
- 4.1.2 is in the public domain by use and/or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of the Receiving Party;
- 4.1.3 is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party;
- 4.1.4 is developed by the Receiving Party independently of Information received from the Disclosing Party, as documented by the Receiving Party’s business records;
- 4.1.5 is disclosed to governmental or other regulatory agencies in order to obtain and/or maintain patents or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain and/or maintain patents or authorizations;
- 4.1.6 is deemed reasonably necessary by Merck to be disclosed to Related Parties, agent(s), consultant(s), and/or other Third Parties for the research and development, manufacturing and/or marketing of the Product (or for such entities to determine their interest in

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performing such activities) in accordance with this Agreement on the condition that such Related Parties and Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; or

- 4.1.7 is deemed necessary by counsel to the Receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by the confidentiality and non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than [*] .

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

If a Receiving Party is required by judicial or administrative process to disclose Information that is subject to the non-disclosure provisions of this Section 4.1 or Section 4.2, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 4.1 and Section 4.2, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

- 4.2 **Dynavax Know-How.** Dynavax agrees to (a) keep, and to cause its Affiliates to keep, all Dynavax Know-How relating to Licensed Vaccine and/or Product confidential so long as such information remains subject to Section 4.1 as applied to Merck as the receiving party thereof; and (b) to not use, or permit a Third Party to use Dynavax Know-How with respect to Licensed Vaccine and/or Product in the Field in the Territory, except to fulfill its obligations under this Agreement.

- 4.3 **Publication.** Merck and Dynavax each acknowledge the other Party's interest in publishing the results of its research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 4.1, either Party, its Affiliates, Related Parties, its employees or consultants wishing to make a publication shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least (a) in the case of an abstract, [*] prior to submission for publication or presentation; or (b) in the case of all other publications, [*] prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party

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requests a delay, the publishing Party shall delay submission or presentation for a period of [*], extendable by written letter agreement, to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 7. Upon expiration of such [*] and absent a written letter agreement to extend such [*] period, the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation.

4.4 Publicity/Use of Names. No disclosure of the existence or the terms of this Agreement may be made by either Party (or its respective Affiliates), and no Party (or its respective Affiliates) shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law; provided, however, if Merck desires to use any trademark identified by Dynavax as of the Effective Date for use for the Licensed Vaccine and/or Product in the Territory (excluding the trademark Dynavax™, but including without limitation the trademark Heplisav™), in connection with the marketing, promotion and/or sale of Product, Dynavax shall grant Merck a non-exclusive, royalty-free, perpetual license to such trademark(s), with a right of sublicense, solely for the marketing, promotion and sale of Products in the Field in the Territory in accordance with this Agreement.

The Parties acknowledge and agree that, upon and/or following the Effective Date, the Parties shall issue a joint press release announcing the execution of this Agreement. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press release prior to the issuance thereof; provided, however, that neither Party shall issue any such press release without the other Party's consent, which may not be unreasonably withheld. Either Party may issue such press releases or otherwise make such public statements or disclosures (such as in annual reports to stockholders or filings with the Securities and Exchange Commission) as it determines in good faith based on advice of counsel, are reasonably necessary to comply with applicable public disclosure laws and regulations; provided, however, to the extent practicable (i) a Party shall not issue any such press releases or make such statements or disclosures without the other Party's prior review and comment and (ii) each Party shall provide the other Party with no less than [*] prior review for each such press release unless an otherwise shorter period of time is required under applicable public disclosure laws and regulations. In addition, following any initial press release(s) announcing this Agreement or other public disclosure approved by both Parties, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith. [*].

ARTICLE 5 PAYMENTS; ROYALTIES AND REPORTS

5.1 Up Front License Fee. Subject to the terms and conditions of this Agreement, in consideration for the licenses granted to Merck in Section 3.1.1 and Section 3.2, and the other rights granted to Merck under this Agreement, Merck shall pay to Dynavax a non-refundable, non-creditable license fee of [*] within [*] after the Effective Date.

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5.2 Development Funding.

- 5.2.1 **Development Program Funding.** Subject to the terms and conditions of this Agreement, Merck shall reimburse Dynavax for Dynavax's work on the Development Program under the Development Plan in accordance with Section 2.3 pursuant to the Development Budget.
- 5.2.2 **Additional Development Program Funding.** Subject to the terms and conditions of this Agreement, Merck will pay Dynavax the non-refundable, non-creditable amount of [*] within [*] after the Effective Date for development work conducted by Dynavax prior to the Effective Date; provided that Merck shall remain responsible for reimbursing Dynavax for work performed by Dynavax during the Not Incurred Expense Period in accordance with Section 2.3.1 and Section 2.3.3.

5.3 Milestone Payments.

- 5.3.1 **Development Milestones.** Subject to the terms and conditions of this Agreement, Merck shall pay to Dynavax the following non-refundable, non-creditable development milestone amounts upon [*]:
- (a) [*];
 - (b) [*]; and
 - (c) [*].
- 5.3.2 **Sales Milestone.** Merck shall pay to Dynavax the following non-refundable, non-creditable sales milestone amounts upon [*]:
- (a) [*];
 - (b) [*];
 - (c) [*]; and
 - (d) [*].
- 5.3.3 Merck shall notify Dynavax in writing and pay the applicable amount within [*] following the achievement of each milestone under Section 5.3.1. Each milestone payment shall be payable only upon the initial achievement of the respective milestone event and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone event.

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5.4 Royalties.

5.4.1 **Royalties Payable By Merck.**

- (a) **Royalty Rate.** Subject to the terms and conditions of this Agreement, including without limitation the remaining provision of this Section 5.4, Merck shall pay Dynavax royalties in an amount equal to the following percentage of Net Sales of Products by Merck or its Related Parties:
- (i) [*];
 - (ii) [*]; and
 - (iii) [*].
- (b) **Royalty Term.** Merck obligation to pay royalties on Net Sales of Product at the rates set forth above shall continue [*].
- (c) **Additional Conditions.** All royalties are subject to the following conditions:
- (i) that only one royalty shall be due with respect to the same unit of Product;
 - (ii) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Net Sales to the first independent Third Party;
 - (iii) no royalties shall accrue on the sale or other disposition of Product by Merck or its Related Parties for use in a Clinical Trial; and
 - (iv) no royalties shall accrue on the disposition of Product in reasonable quantities by Merck or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).

5.4.2 **Change in Sales Practices.** The Parties acknowledge that during the term of this Agreement, Merck's sales practices for the marketing and distribution of Product may change to the extent to which the calculation of the payment for royalties on Net Sales may become impractical or even impossible. In such event the Parties agree to meet and discuss in good faith new ways of compensating Dynavax to effect the same economic outcome contemplated under Section 5.4.1.

5.4.3 **Royalties for Bulk Licensed Vaccine.** In those cases in which Merck sells bulk Licensed Vaccine rather than Product in packaged form to an independent Third Party, the royalty obligations of this Section 5.4 shall be applicable to the bulk Licensed Vaccine; provided that and for the purposes of clarity, in no event shall any Related Party (including with out limitation [*] in the event that it obtains rights to Licensed Vaccine

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and Product under any rights licensed to Merck by Dynavax under this Agreement under Sections 3.1.1 or 3.2) be considered an independent Third Party under the foregoing.

- 5.4.4 **Compulsory Licenses.** If a compulsory license is granted to a Third Party with respect to Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Section 5.4.1, then the royalty rate to be paid by Merck on Net Sales in that country under Section 5.4.1 shall be reduced to the rate paid by the compulsory licensee.
- 5.4.5 **Third Party Licenses.** In the event that one or more licenses from Third Parties identified after the Effective Date are required by Merck or its Related Parties in order to make, have made, use, offer to sell, sell or import Licensed Vaccine or Product(s) in the Territory in the Field (hereinafter “**Third Party Licenses**”), [*] of the royalties actually paid under such Third Party Licenses by Merck or its Related Parties for sale of such Licensed Vaccine or Product shall be creditable against the royalty payments due Dynavax by Merck with respect to the sale of such Licensed Vaccine or Products; provided, however, that in no event shall any royalties otherwise owed by Merck to Dynavax in any affected Calendar Quarter be reduced by more than [*]. For clarity, royalties to Third Parties for [*] as well as royalties for Third Party Licenses identified or in effect as of the Effective Date shall not be deemed Third Party Licenses hereunder.
- 5.4.6 **Competitive Product.** Notwithstanding anything else to the contrary in this Section 5.4, in the event that sales of a Competitive Product [*] sold by a party other than Merck or its Related Parties has or attains on a Calendar Year basis [*], then the royalty rate to be paid by Merck on Net Sales of Product in that country under subsection 5.4.1 shall be [*].
- 5.5 **Reports; Payment of Royalty.** During the term of this Agreement following the First Commercial Sale of a Product, Merck shall furnish to Dynavax a quarterly written report for the Calendar Quarter showing the Net Sales of all Products subject to royalty payments sold by Merck and its Related Parties on a country by country basis in the Territory during the reporting period and the royalties payable under this Agreement. Reports shall be due on the [*] following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.
- 5.6 **Audits.**
- 5.6.1 Upon the written request of Dynavax and not more than [*] in each Calendar Year, Merck shall permit an independent certified public accounting firm of nationally recognized standing selected by Dynavax and reasonably acceptable to Merck, at Dynavax’s expense, to have access during normal business hours to such of the records of Merck as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than [*] prior to the date of such request. The accounting firm shall disclose to Dynavax whether the royalty reports are correct or incorrect, a reasonably specific summary of the basis for such incorrect reporting and the amount of any discrepancy.

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- 5.6.2 If such accounting firm identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within [*] of the date Dynavax delivers to Merck such accounting firm's written report with its conclusions, or earlier as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Dynavax; provided, however, if such audit uncovers an underpayment of royalties by Merck that exceed [*], then the fees of such accounting firm shall be paid by Merck. Nothing in the foregoing sentence shall limit Merck's right to refer any dispute on the interpretation of any provision of this Agreement to dispute resolution pursuant to Section 12.6.
- 5.6.3 Merck shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Merck, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Dynavax's independent accountant to the same extent required of Merck under this Agreement. Moreover, Merck shall inform Dynavax of the results of any Related Party audits conducted by Merck that identify any underpayment or overpayments of royalties owed to Dynavax identified in such audit.
- 5.6.4 Upon the expiration of [*] following the end of any Calendar Year, the calculation of royalties payable with respect to such year shall be binding and conclusive upon Dynavax, and Merck and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.
- 5.6.5 Dynavax shall treat all financial information subject to review under this Section 5.6 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Merck and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

5.7 **Payment Exchange Rate.** All payments to be made by Merck to Dynavax under this Agreement shall be made in United States dollars and may be paid by check made to the order of Dynavax or bank wire transfer in immediately available funds to such bank account in the United States as listed below or as otherwise may be designated in writing by Dynavax from time to time:

[*]

In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due Dynavax shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system (which as of the Effective Date is the applicable rate quoted by [*]), prevailing on the third to the last business day of the month preceding the month in which such sales are recorded by Merck.

5.8 **Income Tax Withholding.** If applicable laws, rules or regulations require withholding of income or other taxes imposed upon any payments made by Merck to Dynavax under Article 5, Merck shall make such withholding payments as may be required and shall subtract such withholding payments from such payments. Merck shall submit appropriate proof of payment of the withholding taxes to Dynavax within a reasonable period of time. Merck shall promptly provide Dynavax with the official receipts. Merck shall render Dynavax reasonable assistance in order to

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allow Dynavax to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. If Merck had a duty to withhold taxes in connection with any payment it made to Dynavax under the Agreement but Merck failed to withhold, and such taxes were assessed against and paid by Merck, then Dynavax will reimburse Merck for such taxes (including any interest charged Merck on such taxes). If Merck makes a claim under this Section, it will comply with the obligations imposed by this Section as if Merck had withheld taxes from a payment to Dynavax.

ARTICLE 6 REPRESENTATIONS AND WARRANTIES

6.1 REPRESENTATIONS AND WARRANTIES OF EACH PARTY. Each Party represents and warrants to the other Party that as of the Effective Date:

- 6.1.1 it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and
- 6.1.2 this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

6.2 DYNAVAX REPRESENTATIONS AND WARRANTIES. Dynavax represents and warrants to Merck that as of the Effective Date:

- 6.2.1 to Dynavax's knowledge, the Dynavax Patent Rights and Dynavax Know-How exist and are not invalid or unenforceable, in whole or in part;
- 6.2.2 it has the full right, power and authority to perform the Development Program and to grant the licenses granted by Dynavax under Article 3;
- 6.2.3 it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Dynavax Patent Rights or Dynavax Know-How with respect to the Licensed Vaccine or the Product in the Field in the Territory;
- 6.2.4 to Dynavax's knowledge, it is the sole and exclusive owner of the Dynavax Patent Rights set forth in Schedule 1.26 and Dynavax Know-How, all of which are (and shall be, in the case of Dynavax Information and Invention) free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Dynavax Patent Rights (except as to rights licensed to Dynavax, including its rights under the [*]) and Dynavax Know-How other than as provided under this Agreement;
- 6.2.5 [*];

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- 6.2.6 there are no claims, judgments or settlements against or owed by Dynavax and no pending or threatened claims or litigation relating to the Dynavax Patent Rights and Dynavax Know-How;
- 6.2.7 Dynavax has disclosed to Merck all reasonably relevant information known to it regarding the Dynavax Patent Rights and Dynavax Know-How licensed under this Agreement, including without limitation all patent opinions obtained by Dynavax related thereto;
- 6.2.8 Schedule 6.2.8 sets forth all IND(s) covering the Licensed Vaccine under development by Dynavax as of the Effective Date (collectively, the “**Dynavax IND**”) and all such Dynavax IND(s) are (i) owned and under the exclusive control of Dynavax, (ii) are in good standing with the FDA and other Regulatory Authorities, and (iii) have not been, and are not currently, subject to any clinical hold by any Regulatory Authority;
- 6.2.9 Dynavax is in compliance with the Dynavax IND; and neither Dynavax, nor any officer, employee or agent of Dynavax, made any untrue statement of a material fact to the FDA or any regulatory Authority or knowingly failed to disclose a material fact required to be disclosed to the FDA or any Regulatory Authority in connection with seeking any Dynavax IND; and (iii) other than the Dynavax INDs disclosed on Schedule 6.2.8, neither Dynavax nor any of its Affiliates have made any filing for an IND with any Regulatory Authority with respect to any vaccine incorporating a Hepatitis B Surface Antigen and 1018 ISS;
- 6.2.10 except for customary ongoing reporting and administrative requirements and except as otherwise disclosed in publicly available FDA records and filings, there are no outstanding material commitments or obligations of Dynavax to the FDA or any other Regulatory Authority with respect to the Dynavax IND or any IND covering a Hepatitis B Surface Antigen or 1018 ISS;
- 6.2.11 Dynavax has provided access to Merck, if any, of all serious and unexpected adverse experience reports and periodic adverse experience reports, IND safety reports (written, in person, telephonic, and/or facsimile transmission safety reports) with respect to the Licensed Vaccine, the Hepatitis B Surface Antigen and/or 1018 ISS that have been filed by Dynavax with the FDA or any other Regulatory Authority, including any correspondence relating thereto;
- 6.2.12 to Dynavax’s knowledge, there is no action or proceeding by the FDA or any other Regulatory Authority pending or threatened seeking the revocation or suspension of any Dynavax IND or any other IND relating to the Hepatitis B Surface Antigen and/or 1018 ISS, in the Territory, which shall include without limitation any clinical hold or similar orders;
- 6.2.13 Dynavax has made available to Merck all material written communications, written records of any telephone IND safety reports and contact information between Dynavax and FDA or any Regulatory Authority with regard to the Licensed Vaccine, the Hepatitis B Surface Antigen and/or 1018 ISS;

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- 6.2.14 Dynavax has disclosed to Merck all scientific, technical and other information in the possession of Dynavax or its Affiliates that is material to the safety and efficacy of the Licensed Vaccine, Product, the Hepatitis B Surface Antigen and/or 1018 ISS, which includes, without limitation, any information generated from any Dynavax INDs;
- 6.2.15 Neither Dynavax nor any of its Affiliates is currently subject to an FDA consent decree or any other similar action of a Regulatory Authority;
- 6.2.16 Schedule 6.2.16 contains a true, correct and complete copy of the [*] and such copy includes any and all amendments, restatements, side letters, or other modifications thereto, in effect as of the Effective Date, and that such copies have been redacted of only financial terms and other provisions that taken collectively do not, and will not, materially effect any rights under the [*] that have been sublicensed to Merck under this Agreement; and
- 6.2.17 (i) Dynavax is not in breach, material or otherwise, of the [*] and has not received any notice or claim by [*] alleging any breach by Dynavax thereunder, and (ii) under the [*] Dynavax has the right to sublicense all patent rights granted to Dynavax as identified under the [*] as Dynavax Patent Rights, to Merck consistent with the licenses granted to Merck within the Hep B Field by Dynavax under Sections 3.1.1 and 3.2.

6.3 Disclaimer of Warranties. The warranties expressly provided in this Agreement are the sole warranties given by the Parties hereunder, and are made expressly in lieu of, and exclude, any implied warranties of merchantability, fitness for a particular purpose, non-infringement or otherwise, and all other express or implied representations and warranties provided by common law, statute or otherwise are hereby disclaimed by both Parties.

6.4 Limitation on Damages to Other Party. In no event will either Party be liable for any punitive, special, indirect, consequential, incidental or exemplary damages or similar damages or losses to the other Party arising out of this agreement or the exercise of its rights hereunder, including but not limited to lost profits, regardless of whether arising from breach of contract, warranty, tort, strict liability or otherwise, even if the Party is advised of the possibility of such loss or damage or if such loss or damage could have been reasonably foreseen; provided, however, the foregoing limitation of liability shall not apply to the liabilities arising from a Party's gross negligence or willful misconduct and this Section 6.4 shall not be construed to limit either Party's indemnification obligations under Sections 11.1 or 11.2 or a Party's right to obtain such damages for a breach of Article 4.

ARTICLE 7 PATENT PROVISIONS.

7.1 Filing, Prosecution and Maintenance of Patents. Dynavax agrees to file, prosecute and maintain in the Territory, in consultation with Merck, the Dynavax Patent Rights licensed to Merck under this Agreement; provided, however, that with respect to Joint Information and Inventions, the Parties agree to select outside counsel acceptable to both Parties to file, prosecute and maintain in the Territory, upon appropriate consultation with the Parties, patent applications and patents with respect to Joint Information and Inventions and such outside counsel will be instructed to keep both Parties informed of all matters, give both Parties appropriate time to review all filings and consider in good faith the comments of both Parties on all filings. The

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costs, fees and expenses related to patent applications and patents for Joint Information and Inventions shall be shared equally by Dynavax and Merck. If either party elects not to file a patent application on Joint Information and Inventions, it shall notify the other Party and the other Party shall have the right to file such patent applications. In such event, the non-filing Party shall execute such documents and perform such acts at the non-filing Party's expense as may be reasonably necessary to effect an assignment of such Joint Information and Inventions to the other Party in a timely manner to allow the other Party to assume such prosecution or maintenance. With respect to Dynavax Information and Inventions and Dynavax Patent Rights, Dynavax may elect not to file and if so, Dynavax shall notify Merck and Merck shall have the right to file such patent applications. In such event, Dynavax shall execute such documents and perform such acts at Dynavax's expense as may be reasonably necessary to effect an assignment of such Dynavax Patent Rights to Merck in a timely manner to allow Merck to continue such prosecution or maintenance. In each case, the filing Party shall give the non-filing Party an opportunity to review the text of the application before filing, shall consult with the non-filing Party with respect thereto, and shall supply the non-filing Party with a copy of the application as filed, together with notice of its filing date and serial number. Each Party shall keep the other Party advised of the status of the actual and prospective patent filings and upon request, shall provide advance copies of any papers related to the filing, prosecution and maintenance of such patent filings. Dynavax shall promptly give notice to Merck of the grant, lapse, revocation, surrender, invalidation or abandonment of any Dynavax Patent Rights licensed to Merck for which Dynavax is responsible for the filing, prosecution and maintenance. With respect to all filings hereunder, the filing Party shall be responsible for payment of all costs and expenses related to such filings. Any patents or patent applications assigned hereunder shall not be considered patent rights of the Party executing such assignment.

7.2 Interference, Opposition, Reexamination and Reissue.

- 7.2.1 Dynavax shall, within [*] of notice of an interference, opposition, reexamination or reissue with respect to Dynavax Patent Rights, inform Merck of such event. If any claim of the patent involved covers Merck's activities in the Field, Merck and Dynavax shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Merck shall have the right to review and consult with respect to any submission to be made in connection with such proceeding.
- 7.2.2 Dynavax shall not initiate any reexamination, interference or reissue proceeding relating to Dynavax Patent Rights within the Field without the prior written consent of Merck, which consent shall not be unreasonably withheld.
- 7.2.3 In connection with any interference, opposition, reissue, or reexamination proceeding relating to Dynavax Patent Rights within the Field, Merck and Dynavax will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Dynavax shall keep Merck informed of developments in any such action or proceeding, including, to the extent permissible by law and attorney-client privilege, consultation with respect to any settlement, the status of any settlement negotiations and the terms of any offer related thereto.
- 7.2.4 Dynavax shall bear the expense of any interference, opposition, reexamination, or reissue proceeding relating to Dynavax Patent Rights.

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7.3 Enforcement and Defense.

- 7.3.1 Dynavax shall give Merck notice of either (i) any infringement of Dynavax Patent Rights within the Field, or (ii) any misappropriation or misuse within the Field of Dynavax Know-How, that may come to Dynavax's attention. Merck and Dynavax shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Merck and Dynavax, to terminate any infringement of Dynavax Patent Rights or any misappropriation or misuse of Dynavax Know-How. However, Dynavax, upon notice to Merck, shall have the first right to initiate and prosecute such legal action at its own expense and in the name of Dynavax and Merck, or to control the defense of any declaratory judgment action relating to Dynavax Patent Rights or Dynavax Know-How. Dynavax shall promptly inform Merck if it elects not to exercise such first right and Merck shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Merck and, if necessary, Dynavax. Each Party shall have the right to be represented by counsel of its own choice at such Party's sole expense.
- 7.3.2 In the event that Dynavax elects not to initiate and prosecute an action as provided in Section 7.3.1, and Merck elects to do so, the costs of any agreed-upon course of action to terminate infringement of Dynavax Patent Rights or misappropriation or misuse of Dynavax Know-How, including without limitation the costs of any legal action commenced or the defense of any declaratory judgment, shall be borne by Merck.
- 7.3.3 For any action to terminate any infringement of Dynavax Patent Rights or any misappropriation or misuse of Dynavax Know-How, in the event that Merck is unable to initiate or prosecute such action solely in its own name under Section 7.3.2, Dynavax will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action, Merck and Dynavax will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law and attorney-client privilege, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.
- 7.3.4 Any recovery obtained by either or both Merck and Dynavax in connection with or as a result of any action contemplated by this Section, whether by settlement or otherwise, shall be shared in order as follows:
- (a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;
 - (b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and
 - (c) the amount of any recovery remaining shall then be allocated between the Parties on a pro rata basis taking into consideration the relative economic losses suffered by each Party.

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7.3.5 Dynavax shall inform Merck of any certification regarding any Dynavax Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions or any similar provisions in a country in the Territory other than the United States, and shall provide Merck with a copy of such certification within five (5) business days of receipt. Dynavax's and Merck's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 7.3.1 through 7.3.4; provided, however, that Dynavax shall exercise its first right to initiate and prosecute any action and shall inform Merck of such decision within [*] of receipt of the certification, after which time Merck shall have the right to initiate and prosecute such action. Regardless of which Party has the right to initiate and prosecute such action, both Parties shall, as soon as practicable after receiving notice of such certification, convene and consult with each other regarding the appropriate course of conduct for such action. The non-initiating Party shall have the right to be kept fully informed and participate in decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action.

7.4 **Patent Term Restoration.** The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for United States patents and patent applications. The Parties shall cooperate with each other, including without limitation to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents for Dynavax Patent Rights in any country in the Territory where applicable. Dynavax shall be responsible for all costs associated with obtaining patent term restoration, supplemental protection certificates or their equivalents.

ARTICLE 8 TECHNOLOGY TRANSFER AND MANUFACTURING AND SUPPLY OBLIGATIONS.

8.1 **Commitment.** Pursuant and subject to the terms and conditions of the Manufacturing Agreement, Dynavax agrees to manufacture and supply Merck and Related Parties with all of their requirements, and Merck [*] Dynavax as the manufacturer and supplier of (i) the Hepatitis B Surface Antigen for use with Licensed Vaccine and Product under and during the term of this Agreement; and (ii) the Licensed Vaccine and the Product, in the case of this clause (ii) until such time that (A) the process technology transfer and analytical method transfer from Dynavax to Merck is completed, and (B) Merck determines that such process technology transfer and analytical method transfer is validated and can be filed with a Regulatory Authority, each of (A) and (B) as provided in the Manufacturing Agreement.

8.2 **Process Transfer.** Pursuant and subject to the terms and conditions of the Manufacturing Agreement, Dynavax shall transfer the process technology and analytical methods to Merck, its Affiliates or Third Party manufacturer necessary to allow Merck to replicate the process employed by Dynavax or its Third Party manufacturer to manufacture the Licensed Vaccine or Product at commercial scale at a site to be designated by Merck. Merck will periodically inform Dynavax of the status of transfer. Dynavax shall allow, and cause its Third Party manufacturers to allow Merck employees or agents to reasonably observe the manufacturing of Licensed Vaccine or Product. Upon completion of the process technology transfer, Dynavax will continue, and will cause its Third Party's to continue, to be reasonably available to Merck and will provide,

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at Merck's expense for third Party support only, reasonable assistance requested by Merck in connection with the establishment and implementation of such manufacturing. For clarity, the provisions of this Section 8.2 shall not alter, limit or otherwise amend Dynavax's obligation to supply and Merck's obligation to purchase, pursuant to the Manufacturing Agreement, Hepatitis B Surface Antigen during the term of this Agreement.

8.3 Clinical Supply. Until the technology transfer is completed under Section 10.2 of the Manufacturing Agreement, Dynavax shall, or cause its Third Party manufacturer, to manufacture and supply Merck, and Merck shall order from Dynavax all of its requirements for Licensed Vaccine or Product for use in Clinical Trials to be performed in accordance with the Development Plan (the "**Clinical Product**"). The JDT shall provide Dynavax with a forecast of Clinical Product requirements as part of the Development Plan as specified in Section 2.4.5(a). Dynavax represents and warrants that the Clinical Product shall (i) meet the specifications as agreed to by the Parties; (ii) be manufactured and delivered to Merck in accordance with cGMP, cGLP, and the IND; and (iii) not be adulterated or misbranded within the meaning of the Act. All manufacture and supply of Clinical Product hereunder shall be initiated by purchase orders placed by Merck. Each purchase order shall include the quantity of Clinical Product ordered, requested delivery date(s), and shipping destination and/or instruction. Dynavax shall accept and fill all purchase orders for Clinical Product placed by Merck hereunder, and shall deliver the Clinical Product by the delivery dates requested therein; provided that [*]. Dynavax shall provide all Clinical Product ordered herein [*].

8.4 [*] of Dynavax for Manufacturing. Subject to the terms and conditions of this Agreement and the Manufacturing Agreement, Merck hereby [*] Dynavax, and Dynavax accepts such [*], on Merck's behalf to perform itself (or through its Affiliates or Third Parties as permitted in accordance with Section 2.2) the manufacture and supply of Clinical Product and the commercial supply of Hepatitis B Surface Antigen for Merck and its Related Parties in accordance with this Article 8 and the Manufacturing Agreement.

ARTICLE 9 REGULATORY

9.1 Regulatory.

9.1.1 **Regulatory Responsibilities.** Merck, or its designee, shall have primarily responsibility and control for all regulatory filings, communications and correspondence with the Regulatory Authorities relating to Licensed Vaccine and/or Product in the Territory and should hold the BLA and, after the transfer of the INDs in accordance with Section 9.1.2, the IND. Subject to the assistance of Dynavax as specified below, Merck, at its sole expense, shall be responsible for timely performing all regulatory activities which it deems necessary for Licensed Vaccine and Products in the Territory. Merck shall consult with Dynavax with respect to its regulatory strategy and consult with Dynavax prior to any filings with Regulatory Authorities, provide a copy of all filings, communications and correspondence with Regulatory Authorities relating to Licensed Vaccine and/or Product in the Territory and allow Dynavax to participate in any meetings with Regulatory Authorities in the United States. Dynavax will assist Merck in establishing and maintaining filings with the Regulatory Authorities, including the IND and any BLA, and participate and/or assist in communication and correspondence with the Regulatory Authorities as set forth in Schedule 9.1 attached hereto. Merck shall fund the regulatory

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assistance that Dynavax provides to Merck to obtain Regulatory Authorizations for the Product in accordance with this Section 9.1.1 as set forth in Section 2.3. Merck may utilize the services of its Affiliates and Third Parties to perform its regulatory responsibilities and Dynavax may utilize the services of its Affiliates and Third Parties to perform its regulatory responsibilities only with Merck's prior written consent and otherwise in accordance with Section 2.2.

- 9.1.2 **Transfer of Regulatory Filing To Merck.** As soon as practicable after the Effective Date, but in no event later than [*] after the Effective Date, Dynavax shall, at Merck's expense, transfer and assign to Merck (or its designee) any and all Dynavax INDs for Licensed Vaccine or Product in the Territory and, upon completion of such transfer, Merck shall assume complete ownership of and responsibility for all Dynavax INDs. Prior to Dynavax's transfer of the INDs to Merck in accordance with the foregoing, subject in all cases to prior consultation with, and approval from, Merck, Dynavax shall take all reasonable or necessary steps to properly maintain the Dynavax INDs with the Regulatory Authority. Dynavax hereby provides Merck with a right of reference to and agrees to properly maintain with applicable Regulatory Authority any and all Drug Master Files that cover, in whole or in part, Licensed Vaccine and/or Products which are in Dynavax's or its Affiliate's possession or control as of the Effective Date.

9.2 Adverse Experience Reporting.

- 9.2.1 Dynavax agrees throughout the duration of this agreement to notify Merck within the earlier of [*] and [*], in English of any information of which Dynavax becomes aware concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, whether or not determined to be attributable to any Licensed Vaccine and/or Product (hereinafter "**Adverse Experience**"), where such Adverse Experience is (i) serious and associated with the clinical uses, studies, investigations, tests and marketing of Product (to the extent performed or is the responsibility of Dynavax), whether or not determined to be attributable to Product. With respect to all other adverse experiences (non-serious expected or non-serious unexpected adverse experiences), Dynavax shall furnish Merck with copies of such non-serious adverse experiences reported to Dynavax in connection with the marketing of Product, in English, within [*] after receipt. "**Serious**" as used in this Section refers to an experience which results in death, is immediately life threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization, or prolongation of existing hospitalization, or is a congenital anomaly, cancer or an overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes previously listed should also be considered serious. "**Unexpected**" as used in this Section refers to a condition or development not listed in the current labeling or investigator's brochure for Product, and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of increased frequency or greater severity or specificity.
- 9.2.2 With respect to clinical trials being carried out by or on behalf of Dynavax, adverse experience reports of unexpected and fatal or life-threatening events which are possibly, probably, definitely related or of unknown relationship to the use of Product must be forwarded to Merck within [*] after receipt of the information. In addition, Dynavax

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shall furnish to Merck copies of the end of study summary of adverse experiences in English within the time period set forth in the applicable then-current clinical development plan for Product.

- 9.2.3 It is understood and agreed that these adverse experience reporting requirement provisions are based on the policies and procedures of Merck and regulatory reporting requirements. In the event of changes to regulatory requirements for adverse experience reporting, Merck shall promptly notify Dynavax of any such changes and Dynavax agrees to comply with any such reasonably required revised notification requirements applicable to Merck and other parties generally subject to the Merck procedures.
- 9.2.4 By no later than [*] after the Effective Date the Parties shall meet to discuss the details and implementation of a formal procedure for the mutual exchange of adverse event reports and safety information associated with the Licensed Vaccine and/or the Product. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed pharmacovigilance agreement between the Parties which that Parties shall endeavor to finalize within [*] following the Effective Date. Such pharmacovigilance agreement shall be implemented at a time sufficient to permit compliance with applicable Regulatory Authority guidelines and regulations.

Article 10 TERM AND TERMINATION

10.1 Term and Expiration. This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 10.2 or 10.3, this Agreement shall continue in effect until expiration of all payment obligations of Merck to Dynavax under Article 5. Upon expiration of this Agreement, Merck's licenses pursuant to Sections 3.1.1 and 3.2 shall become fully paid-up, perpetual licenses.

10.2 Termination by Either Party.

- 10.2.1 **Termination By Merck.** Notwithstanding anything contained herein to the contrary, Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving [*] advance written notice to Dynavax.
- 10.2.2 **Termination by Dynavax.** In the event that Merck provides Dynavax with a Ceased Development Notice under Section 3.3 and [*], Dynavax shall have the right to terminate this Agreement in its sole discretion by giving [*] advance written notice to Merck.

10.3 Termination for Cause. This Agreement may be terminated at any time during the term of this Agreement:

- 10.3.1 upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within [*] after notice requesting cure of the breach; provided, however, in the event of a good faith dispute with respect to the existence of a material breach, the [*]

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cure period shall be tolled until such time as the dispute is resolved pursuant to Section 12.6; or

10.3.2 by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [*] after the filing thereof.

10.4 Effect of Certain Terminations.

10.4.1 If Merck terminates this Agreement under Section 10.3.1, [*]; and (b) Dynavax shall, within [*] after the effective date of such termination return or cause to be returned to Merck all Materials provided to it by Merck, all Licensed Vaccine and Product, all Information in tangible form, and all substances or compositions, in each case delivered or provided by Merck, as well as any other material provided by Merck in any medium; provided, however, that Dynavax may keep one copy of Information received from Merck (and/or its Affiliates) in its confidential files for record purposes.

10.4.2 If Dynavax terminates this Agreement under Section 10.3.1, subject to Section 10.4.3(d), [*].

10.4.3 Upon termination of this Agreement by Merck pursuant to Section 10.2.1, or by Dynavax pursuant to Section 10.2.2 or Section 10.3.1:

- (a) Subject to Section 10.4.3(e), no later than thirty (30) days after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information received from the other Party and all copies thereof; provided, however, that each Party may keep one copy of Information received from the other Party in its confidential files for record purposes;
 - (b) Subject to Section 0, each Party shall pay all amounts then due and owing as of the termination date;
 - (c) [*];
 - (d) [*];
 - (e) [*]:
 - (i) [*];
 - (ii) [*]; and
 - (iii) [*];
- [*].

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[*].

10.4.4 If this Agreement is terminated by Merck pursuant to Section 10.3.2 due to the rejection of this Agreement by or on behalf of Dynavax under Section 365 of the United States Bankruptcy Code (the "Code"), all licenses and rights to licenses granted under or pursuant to this Agreement by Dynavax to Merck are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against Dynavax under the Code, which proceeding is not stayed within [*] after initiation of such proceedings, Merck shall be entitled to a complete duplicate of or complete access to (as Merck deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Merck (i) upon written request therefore by Merck following the expiration of the [*], unless Dynavax elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i), upon the rejection of this Agreement by or on behalf of Dynavax upon written request therefore by Merck.

The foregoing Section 10.4.4 is without prejudice to any rights Merck may have arising under the Code or other applicable law.

10.5 **Effect of Expiration or Termination; Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) or Licensed Vaccine sold prior to such expiration or termination. The provisions of Article 4 shall survive the expiration or termination of this Agreement and shall continue in effect for [*]. In addition, the provisions of Article 1, Section 2.6, Section 2.7, Article 4, Article 6, Article 7, Section 8.2 (if Merck terminates this Agreement under Section 10.3.1), Section 9.2.4, Article 10, Article 11 and Article 12 shall survive any expiration or termination of this Agreement.

ARTICLE 11 INDEMNITY

11.1 **Indemnification By Merck.** Merck shall indemnify, defend and hold Dynavax, its Affiliates and their respective agents, employees, officers and directors (each a "Dynavax Indemnitee") harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, "Losses") to which any Dynavax Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any person or entity other than a Party or its Affiliates to the extent such Losses arise directly or indirectly out of [*]; except, in each case, to the extent such Losses result from the material breach by Dynavax, its Affiliates, sublicensees or subcontractors of any covenant, representation, warranty or other agreement made by Dynavax in this Agreement or the negligence or willful misconduct of any Dynavax Indemnitee.

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- 11.2 Indemnification by Dynavax.** Dynavax shall indemnify, defend and hold Merck, its Affiliates, Related Parties and their respective agents, employees, officers and directors (each a “**Merck Indemnitee**”) harmless from and against any and all Losses, to which any Merck Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any person or entity other than a Party or its Affiliates to the extent such Losses arise directly or indirectly out of [*], to the extent such Losses result from the material breach by Merck, its Related Party or subcontractors of any covenant, representation, warranty or other agreement made by Merck in this Agreement or the negligence or willful misconduct of any Merck Indemnitee.
- 11.3 Notice of Indemnification Obligation and Defense.** Any Party entitled to indemnification under Sections 11.1 or 11.2 shall give notice to the indemnifying Party of any Losses that may be subject to indemnification, promptly after learning of such Losses, but the omission to so notify the indemnifying Party promptly will not relieve the indemnifying Party from any liability under Sections 11.1 or 11.2 except to the extent that the indemnifying Party shall have been prejudiced as a result of the failure or delay in providing such notice. The indemnifying Party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified Party. If such defense is assumed by the indemnifying Party, the indemnifying Party will not be subject to any liability for any settlement of such Losses made by the indemnified Party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified Party with respect to such Losses. The indemnified Party shall provide the indemnifying Party with all information in its possession and all assistance reasonably necessary to enable the indemnifying Party to carry on the defense of any such Losses.

ARTICLE 12 MISCELLANEOUS

- 12.1 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, earthquakes, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

12.2 Assignment/ Change of Control.

- 12.2.1 Except as provided in this Section 12.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party.
- 12.2.2 Merck may, without consent of Dynavax, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of Merck or in connection with a Change of Control of Merck. Dynavax may assign this Agreement in its entirety to the successor party in connection with a Change of Control.

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12.2.3 In the event that there is a Dynavax Change of Control that is a Competing Pharma Change of Control, then Dynavax shall [*] and Merck shall have the right, at Merck election at any time after such Change of Control to implement some or all of the following revisions to this Agreement:

- (a) [*];
- (b) [*];
- (c) [*]; or
- (d) [*].

12.2.4 [*].

12.2.5 Any attempted assignment not in accordance with this Section 12.2 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

12.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

12.4 Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Dynavax, to: Dynavax Technologies Corporation
2929 Seventh Street, Suite 100
Berkeley CA 94710
Attention: Chief Executive Officer
Facsimile No.: 510-848-1376

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and: Cooley Godward Kronish LLP
3175 Hanover Street
Palo Alto, CA 94304-1130
Phone: 650-843-5000

:
Fax: 650-849-7400
Attention: Glen Sato, Esq.

if to Merck, to: Merck & Co., Inc.
[*]

And Merck & Co., Inc.
[*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail.

12.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws.

12.6 Dispute Resolution.

12.6.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an **"Excluded Claim"** shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association ("**AAA**"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

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- 12.6.2 The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within [*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English. The arbitrators shall have the right to provide discovery by the Parties; provided that the period for discovery shall not exceed [*].
- 12.6.3 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.
- 12.6.4 Except to the extent necessary to confirm an award or as may be required by law or regulation, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- 12.6.5 The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.
- 12.6.6 As used in this Section, the term "**Excluded Claim**" shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.
- 12.7 Entire Agreement; Amendments.** This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes and cancels all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

Notwithstanding anything to the contrary in the foregoing, that certain Disclosure Agreement between the Parties dated on or about [*], shall remain in full force and effect with respect to the

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subject matter thereof and information disclosed thereunder; provided that any information disclosed thereunder may be utilized by the Parties for the purposes of this Agreement as if it were disclosed hereunder.

- 12.8 Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- 12.9 Independent Contractors; No Third Party Beneficiaries.** It is expressly agreed that Dynavax and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Dynavax nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party. No person or entity other than Dynavax, Merck and their respective Affiliates and permitted assignees under this Agreement shall be deemed an intended beneficiary under or have any right to enforce any obligation of this Agreement.
- 12.10 Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.
- 12.11 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 12.12 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

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- 12.13 Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa. All references to "dollars" or "\$" in this Agreement shall be a reference to United States dollars, unless otherwise expressly stated.
- 12.14 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.
- 12.15 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 12.16 Affiliates.** Each Party shall cause its respective Affiliates to comply with the terms, conditions, and obligations of this Agreement that are applicable to its Affiliates, and to the extent that a Party performs its obligations, or exercise its rights, under this Agreement through its Affiliate(s) such Party shall cause such Affiliates to comply with the terms, conditions, and obligations applicable to such Party under this Agreement with respect to such obligation and rights.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERCK & CO., INC.

DYNAVAX TECHNOLOGIES CORPORATION

BY: /s/ Richard T. Clark

NAME: Richard T. Clark
TITLE: Chairman, President and
Chief Executive Officer

BY: /s/ Dino Dina

NAME: Dino Dina, M.D.
TITLE: President and Chief Executive Officer

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SCHEDULE 1.26 PATENT RIGHTS

[*]

SCHEDULE 2.1 GENERAL DESCRIPTION OF DEVELOPMENT PLAN

[*]

SCHEDULE 2.3 INITIAL DEVELOPMENT BUDGET

[*]

SCHEDULE 6.2.8 INDs FOR LICENSED VACCINE

[*]

SCHEDULE 6.2.16 [*]

[*]

SCHEDULE 9.1 REGULATORY RESPONSIBILITIES

[*]

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Exhibit 10.35

Execution Copy

MANUFACTURING AGREEMENT
between
DYNAVAX TECHNOLOGIES CORPORATION
and
MERCK & CO., INC.

This Manufacturing Agreement (the "**Agreement**") dated as of October 31, 2007 ("**Effective Date**") is made by and between Dynavax Technologies Corporation ("**Dynavax**"), a corporation organized under the laws of Delaware, and Merck & Co., Inc. ("**Merck**"), a corporation organized under the laws of New Jersey. Each of Dynavax and Merck is sometimes referred to individually herein as a "**Party**" and collectively as the "**Parties**".

WITNESSETH:

WHEREAS, Dynavax and Merck have entered into that certain Exclusive License and Development Collaboration Agreement (the "**License Agreement**"), dated as of the Effective Date under which Dynavax has provided an exclusive license to Merck for its hepatitis B surface antigen ("**Hepatitis B Surface Antigen**") combined with the 1018 ISS (as defined in the License Agreement) in the Hep B Field (as defined in the License Agreement); and

WHEREAS, Merck desires to use the Hepatitis B Surface Antigen, along with the 1018 ISS together with Merck's fill and finish capabilities to sell Licensed Vaccines or Product (as defined herein); and

WHEREAS, until such time that the process and formulation technology transfer from Dynavax to Merck is completed, Dynavax shall supply Merck and Merck shall purchase, its requirements for Licensed Vaccines or Products (solely for use in Clinical Trials (as defined in the License Agreement)), [*]; and

WHEREAS, Merck wishes to engage Dynavax to Manufacture (as defined herein) on Merck's behalf its requirements of Hepatitis B Surface Antigen in accordance with the terms and conditions set forth in this Agreement and the License Agreement.

Now THEREFORE, in consideration of the foregoing premises and mutual covenants herein contained, Dynavax and Merck hereby agree as follows:

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1. DEFINITIONS

As used herein, the following capitalized terms shall have the respective meanings set forth below unless otherwise specifically provided herein and where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the License Agreement:

1.1 “**Act**” shall have the meaning given such term in Section 5.1(a).

1.2 “**Affiliate**” shall have the meaning given such term in the License Agreement.

1.3 “**Agreement**” shall have the meaning given such term in the preamble to this Agreement.

1.4 “**Authorization**” shall mean all approvals or permits granted by a Regulatory Authority necessary to market and sell a Product, including without limitation all applicable pricing and reimbursement approvals, required to sell such Product in a country within the Territory.

1.5 “**BLA**” shall mean the Biologics License Application prepared in accordance with applicable FDA regulations for filings with the FDA for marketing authorization of Product, or its equivalent in other countries within the Territory in conformance with the requirements of the applicable Regulatory Authority.

1.6 “**Calendar Year**” shall mean each successive period of twelve (12) months commencing from January 1 and ending on December 31.

1.7 “**cGMPs**” shall mean all laws and regulations relating to the manufacture of Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, in the USA and European Union, including but not limited to the current Good Manufacturing Practices as specified in the United States Code of Federal Regulations and/or in the European Commission Guide to Good Manufacturing Practice for Medicinal Products (also known as EudraLex Volume 4), Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

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(also known as EudraLex Volume 4 part 2), in each case, as are in effect on the Effective Date and as may be modified or supplemented during the term of this Agreement.

1.8 “**Complete Invoice**” shall have the meaning set forth in Section 8.3.

1.9 “**Delivery**” shall have the meaning set forth in Article 7.

1.10 “**Dose**”; “**Doses**” shall mean the target fill quantity of formulated Hepatitis B Surface Antigen required to fill a vial of Licensed Vaccine or Product for clinical use or commercial sale as more fully described and calculated on Exhibit B attached hereto.

1.11 “**Effective Date**” shall have the meaning given such term in the preamble to this Agreement.

1.12 “**Facility**” shall mean Dynavax’s new Manufacturing facility currently expected to be located at [*] at which Hepatitis B Surface Antigen is Manufactured.

1.13 “**FDA**” shall mean the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.14 “**Firm Order**” shall mean a binding commitment on the part of Merck or its Related Party to purchase, and on the part of Dynavax to supply, certain quantity of Hepatitis B Surface Antigen.

1.15 “**Hepatitis B Surface Antigen**” shall have the meaning given such term in the preamble to this Agreement.

1.16 “**Initial Pricing**” shall have the meaning given such term in Section 8.1.

1.17 “**Initial Pricing Period**” shall have the meaning given such term in Section 8.1.

1.18 “**Know-How**” shall mean, any non-public, documented or otherwise recorded or memorialized knowledge, experience, know-how, technology, information, and data, including formulas and formulations, processes, techniques, unpatented inventions, discoveries, ideas, and

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developments, test procedures, and results, together with all documents and files embodying the foregoing.

1.19 "**Launch**" shall mean, on a country-by-country basis, after receipt of Authorization for Product in any country the first day on which Merck or a Related Party ships Product to a wholesaler or Third Party in such country, excluding however, any sale or other distribution for use in a Clinical Trial in such country.

1.20 "**License Agreement**" shall have the meaning given such term in the preamble to this Agreement.

1.21 "**Licensed Vaccine**" shall have the meaning given such term in the License Agreement.

1.22 "**Live Agent**" shall have the meaning given such term in Section 6.9.

1.23 "**Long Range Forecast**" shall have the meaning set forth in Section 3.1.

1.24 "**Major Market Launch**" shall have the meaning set forth in Section 3.1.

1.25 "**Manufacture**" shall mean all operations of Dynavax involved in (i) the receipt, incoming inspections, storage and handling of Materials and (ii) the manufacturing, warehousing, quality control testing (including in-process, release and stability testing), releasing, and shipping of bulk Hepatitis B Surface Antigen.

1.26 "**Manufacturing Fee**" shall have the meaning set forth in Section 8.1.

1.27 "**Manufacturing Technology**" shall mean all inventions, discoveries, improvements, methods, processes, formulas, Materials, Know-How, trade secrets, technology, data or information Controlled by Dynavax whether patentable or not which are related to the manufacturing process of Hepatitis B Surface Antigen, in the Control of Dynavax or its Affiliates as of the effective date of the License Agreement, or which thereafter become Controlled by Dynavax or its Affiliates and subject to the grant of a license under Section 3.2 of the License Agreement.

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1.28 “**Master Cell Bank(s)**” shall have the meaning given such term in Section 9.1.

1.29 “**Materials**” shall mean all raw materials necessary for the Manufacture of Hepatitis B Surface Antigen, including without limitation, intermediates, components, containers, labels and packaging materials.

1.30 “**MST**” shall have the meaning given such term in Section 4.3.

1.31 “**Party/Parties**” shall have the meaning given such term in the preamble to this Agreement.

1.32 “**Pilot Facility**” shall have the meaning given such term in Section 9.2.

1.33 “**Product**” shall have the meaning given such term in the License Agreement.

1.34 “**Quality Agreement**” shall have the meaning set forth in Section 6.11.

1.35 “**Regulatory Authority**” shall mean any applicable governmental organization, agency or administrative body subject to state supervision which has the authority to grant approvals and regulate pharmaceutical/biological manufacturing, marketing, reimbursement and/or pricing of the Product within the Territory, as applicable.

1.36 “**Related Party**” shall mean Affiliates of Merck, and any sublicensee of Merck, in whole or in part, of the licenses granted by Dynavax to Merck under the License Agreement (which term does not include distributors), as applicable.

1.37 “**Rolling Forecast**” shall have the meaning set forth in Section 3.2.

1.38 “**Specifications**” shall mean manufactured in accordance with cGMPs and those specifications for Hepatitis B Surface Antigen Product as set forth on Exhibit A attached hereto, which can only be changed or modified with the prior written agreement of both Parties.

1.39 “**Steady State Pricing**” shall have the meaning given such term in Section 8.1.

1.40 “**Supply Failure**” shall mean [*].

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1.41 “*Supply Failure Technology Transfer Notice*” shall have the meaning given such term in Section 9.1.

1.42 “*Term*” shall have the meaning set forth in Section 12.1.

1.43 “*Territory*” shall mean any and all countries in the world, and their territories and possessions.

1.44 “*Third Party*” shall mean any or all persons or entities other than Merck and its Related Parties, and Dynavax and its Affiliates.

1.45 “*Working Cell Bank*” shall have the meaning given such term in Section 13.1.

2. [*]; HEPATITIS B SURFACE ANTIGEN SUPPLY; LICENSED VACCINE OR PRODUCT SUPPLY

2.1 Merck hereby [*] Dynavax to act for and on the behalf of Merck and Related Parties to Manufacture and supply the Hepatitis B Surface Antigen for use with Licensed Vaccine and Product, and Dynavax accepts [*] to Manufacture Hepatitis B Surface Antigen for use with Licensed Vaccine or Product. The Parties acknowledge that the use of any Merck Know-How is solely for the performance of [*] hereunder and the retained rights of Dynavax with respect to Dynavax Know-How remain subject to Section 3.1.3 of the License Agreement. As part of its obligations, Dynavax shall supply all Materials necessary to satisfy the production requirements of Merck for Hepatitis B Surface Antigen in accordance with this Agreement. Materials shall remain the property of Dynavax and shall be used by Dynavax for satisfying its exclusive Manufacturing and supply rights to the Hepatitis B Surface Antigen.

2.2 Except as set forth in Sections 3.3, 4.2 and 9.2 below, Dynavax shall supply Merck and Related Parties, and Merck and Related Parties shall purchase from Dynavax, Merck’s total requirements of Hepatitis B Surface Antigen for the manufacture of Licensed Vaccine and Product for commercial sale by Merck and its Related Parties in the Field in the Territory; *provided, however*, that the Parties acknowledge and agree Dynavax’s ability to Manufacture Hepatitis B Surface Antigen is subject to [*]. For the purposes of this Agreement, the reference to the requirement of Merck shall include those of its Related Parties.

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2.3 Dynavax shall supply Merck, and Merck shall purchase from Dynavax, Merck's and its Related Party's total requirements of Licensed Vaccine or Product, as the case may be, for use in Clinical Trials, until [*] (a) [*] and (b) [*] and in any event subject to (i) the terms and conditions of the Development Program (as defined in the License Agreement); and (ii) the capacity constraints of the Pilot Facility and Facility as described in Section 2.2 above. For the avoidance of doubt, the Development Program shall provide order mechanism and Delivery schedule for any Delivery of the Licensed Vaccine or Product ordered in connection with Clinical Trials.

3. FORECASTING AND ORDERING FOR COMMERCIAL SUPPLY OF HEPATITIS B SURFACE ANTIGEN

3.1 Long Range Forecast: At least [*] prior to the expected first Delivery date of Product for the first Launch in the United States or European Market (as defined in the License Agreement) (the "**Major Market Launch**"), the Parties shall discuss the projected annual quantity requirements for the Hepatitis B Surface Antigen for [*]. Thereafter, by December 1st of each Calendar Year, Merck shall provide Dynavax with an updated forecast of its annual requirements for the Hepatitis B Surface Antigen for [*], along with the projected annual quantity requirements for Launch in the Territory, other than the Major Market Launch (the "**Long Range Forecast**"). Merck shall use commercially reasonable efforts to make its long range forecast as accurate as possible. In the event the requirements for Hepatitis B Surface Antigen as set forth in the most recently updated long range forecast are significantly different from those set forth in the Rolling Forecast for the same period, Merck shall, at Dynavax's request, provide to Dynavax an explanation for such difference. The Parties shall discuss in good faith any adjustments to potential capacity and availability of supply based on significant adjustments to the Long Range Forecast, provided that in any event Merck and Dynavax shall only be bound by the Rolling Forecast. For the avoidance of doubt, Dynavax shall not be obligated to supply, and Merck shall not be obligated to purchase, the quantities of Hepatitis B Surface Antigen set forth in the Long Range Forecast.

3.2 Rolling Forecast: At least [*] prior to the expected first Delivery date of Product for the first Major Market Launch, and thereafter, on or before the dates agreed upon by

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the MST, and in any event at least [*], Merck shall provide Dynavax with a good faith forecast of monthly quantity requirements for the Hepatitis B Surface Antigen for [*] (the "**Rolling Forecast**").

3.3 Firm Order: The first [*] of each monthly Rolling Forecast shall be deemed as a Firm Order. Merck shall designate a Delivery date or Delivery date(s) for the Firm Orders. The Parties agree that (i) prior to the [*] of the first Major Market Launch, the [*] of each Firm Order shall not vary by more than [*] of the estimated quantity of the [*] of the previous Rolling Forecast; and (ii) following the [*] of the first Major Market Launch, the [*] of each Firm Order shall not vary by more than [*] of the estimated quantity of the [*] of the previous Rolling Forecast. If Merck places a Firm Order in excess of the maximum amount allowed pursuant to the foregoing sentence, Dynavax shall use its commercially reasonable efforts to meet Merck's request; provided that Dynavax's failure to supply the excess quantities shall not constitute a breach of this Agreement. Notwithstanding the foregoing, the Parties agree that all Rolling Forecasts and Firm Orders shall be subject to the capacity constraints for the Manufacture of Hepatitis B Surface Antigen as described in Section 2.2 above.

3.4 Form of Firm Order: Each Firm Order will be in such form as Merck may specify from time to time in writing; provided that, (a) the terms and conditions of this Agreement shall be controlling over any terms and conditions included in any Firm Order and (b) any term or condition of such Firm Order that is different from or contrary to the terms and conditions of this Agreement shall be null and void and of no force or effect.

3.5 [*]: Merck may [*], provided that (a) a notice is received by Dynavax [*]; and (b) such [*]; and provided further that in any event [*]. Merck acknowledges and agrees that in no event [*].

3.6 Delivery Timing: Dynavax shall satisfy each Firm Order on or before the date specified in such Firm Order by Merck unless otherwise agreed to by Merck. No Deliveries of Hepatitis B Surface Antigen shall be made more than [*] in advance of the date specified for Delivery in a Firm Order without Merck's written approval. Site of Manufacture shall be indicated on documents accompanying each shipment of Hepatitis B Surface Antigen.

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3.7 Pre-Major Market Launch Production: Subject to the capacity restraints set forth in Section 2.2 above, the Parties acknowledge and agree that in order for Dynavax to supply Merck's requirements for Hepatitis B Surface Antigen, Dynavax shall commence Manufacture of the Hepatitis B Surface Antigen prior to the submission of the BLA with the Regulatory Authority. Upon execution of this Agreement, through the JDC, the Parties shall mutually agree upon a commencement date for the Manufacture of the Hepatitis B Surface Antigen and the amount to be produced to support the first Major Market Launch. Merck will issue a Firm Order for such Hepatitis B Surface Antigen to support the first Major Market Launch at least [*] prior to the expected first Major Market Launch. [*]. For the avoidance of doubt, the Parties agree that any Hepatitis B Surface Antigen Delivered under this Section 3.7 shall meet the warranties set forth in Section 5.1(a) in order for [*].

4. ALLOCATION; MANUFACTURING AND SUPPLY TEAM

4.1 Notice: In the event that Hepatitis B Surface Antigen is or is anticipated by Dynavax to be in short supply due to a shortage of Hepatitis B Surface Antigen, Materials, resources or existing capacity, Dynavax shall notify Merck in writing of such circumstances as soon as possible, including the underlying reasons for such anticipated shortage, proposed remedial measures and the date such shortage is expected to end.

4.2 Allocation: In the event of a shortage contemplated in Section 4.1, Dynavax shall allocate to Merck an amount of Hepatitis B Surface Antigen proportionate to the (x) [*], divided by (y) [*]. For clarity, [*]. In making any allocation under this Section 4.2, Dynavax shall [*].

4.3 Manufacturing and Supply Team: No less than [*], the Parties shall establish a manufacturing and supply team (the "**MST**") of a minimum of [*] members, [*] of whom shall be designated by Dynavax and [*] of whom shall be designated by Merck and its Affiliates. The MST shall be deemed to be a sub-team of the JDC (as defined in the License Agreement) and shall substantially follow the procedures of the JDC with respect to meetings and decisions as set forth in Section 2.4 of the License Agreement; provided, however, that the Parties acknowledge and agree that the MST (and related procedures) shall (a) not have the

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authority to bind a Party with respect to manufacturing and ordering except as provided in this Agreement, and (b) in any event survive past either the dissolution of the JDC or the change in function of the JDC pursuant to Section 2.4.4 of the License Agreement. Each Party shall appoint its representatives to the MST by written notice to the other Party and may substitute, from time to time, one or more of its MST representatives, at its sole discretion, effective upon notice to the other Party. The MST representatives of each Party shall have appropriate manufacturing, quality, regulatory and/or technical background, experience and knowledge. The MST shall serve as forum for discussion and resolution of manufacturing, quality, and regulatory issues contained in the BLA and supply chain issues, including, but not limited to scheduling production runs, Delivery forecasts, other production planning, capacity review and metrics. Dynavax shall provide the MST, from time to time, an update of the status, timing, and critical/key issues related to the completion of the Facility and overview of the capacity at the Facility and Pilot Facility compared to the utilization rate of each Facility or Pilot Facility, as the case may be, in order for the MST to identify any potential supply issues of the Hepatitis Surface B Antigen prior to their occurrence. Merck shall provide the MST, from time to time, an update of the status, timing, and critical/key issues in connection with the formulation, filling and packaging processes in connection with Manufacturing the Licensed Vaccines or Product, as the case may be.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 Representations and Warranties:

(a) Dynavax represents, warrants and covenants that (i) the Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, shall, at the time of arrival at the facility designated by Merck, from time to time (A) meet the Specifications; and (B) have been Manufactured in accordance with cGMPs; and (ii) no Hepatitis B Surface Antigen, Licensed Vaccine or Product shall, at the time of Delivery, (A) be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act (the "Act") or (B) have been Manufactured at a Facility that employs any debarred persons pursuant to sections 306(a) and (b) of the Act.

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(b) Dynavax represents, warrants and covenants that, as of the Effective Date: (i) to its knowledge, the Manufacture of Hepatitis B Surface Antigen does not infringe the intellectual property rights of any Third Party in the United States, other than those set forth on Schedule 5.1(b) hereto, or the European Market, as applicable; and (ii) Dynavax has not received written notice from any Third Party of or has no knowledge of (A) any actual or threatened claim or assertion that the Manufacture of Hepatitis B Surface Antigen infringes the intellectual property rights of such Third Party; or (B) any actual or threatened claim or assertion that the use of the Dynavax Manufacturing Technology as contemplated by this Agreement infringes any intellectual property rights of such Third Party in the United States or the European Market, as applicable.

5.2 Expiry Dating: Dynavax represents that [*] for Hepatitis B Surface Antigen. Dynavax shall use its best efforts to extend such dating, such that, subject to Section 3.5, all Hepatitis B Surface Antigen; Licensed Vaccine or Product, as the case may be, supplied by Dynavax under this Agreement will have no less than [*] remaining when Delivered under Section 7.

5.3 Warranty Claims:

(a) Merck shall, within [*] after arrival at the facility designated by Merck, notify Dynavax in writing of any Hepatitis B Surface Antigen, Licensed Vaccine or Product that fails to meet the warranties set forth in Section 5.1(a)(i), and shall notify Dynavax in writing of all other defects within [*] after its discovery of the defect.

(b) Merck shall have the right to perform analytical testing of Hepatitis B Surface Antigen, Licensed Vaccine or Product Delivered, including, without limitation, identification testing. In the event that the tests performed by Merck indicate that a shipment of such Hepatitis B Surface Antigen, Licensed Vaccine or Product does not meet the Specifications, Merck shall promptly notify Dynavax and Dynavax shall, within [*] after its receipt of Merck's notice, use its best efforts to start re-test of such Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, and shall expeditiously complete such testing so that any additional testing by the testing organization that may be required as provided herein-below may

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be completed within [*] of Merck's notice. If the test performed by Merck and the re-test performed by Dynavax reach inconsistent results, the Parties shall, within [*] after the completion of re-test by Dynavax, have Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, sample(s) mutually agreed upon by the Parties tested by a reputable Third Party testing organization selected jointly by the Parties. The Parties agree that such dispute shall not be submitted to arbitration in accordance with Section 12.6.1 of the License Agreement, and the results of such laboratory testing shall be final and binding on the Parties. If the Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be is determined to meet the Specifications by such testing organization, then Merck shall bear the cost of the Third Party testing and pay for such Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, to the extent the Manufacturing Price for such Hepatitis B Surface Antigen has not been paid, or the price agreed to by the Parties in the case of the Licensed Vaccine or Product. If the Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, is determined not to have met the Specifications, then Dynavax shall bear the cost of Third Party testing, and Dynavax shall, within [*], (a) replace the quantity of the Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be affected at no additional cost to Merck, or (b) in the event Dynavax cannot replace the quantity of the Hepatitis B Surface Antigen within such [*] period, then at Merck's election either (i) be granted an additional period of time to be agreed to by the Parties to replace the quantity of the Hepatitis B Surface Antigen or (ii) refund the Manufacturing Price paid by Merck for such Hepatitis B Surface Antigen, or the price agreed to by the Parties in the case of the Licensed Vaccine or Product, and shall in either case, reimburse Merck for any freight, insurance, customs duties and other charges incurred by Merck in connection with Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, that is determined not to meet the Specifications.

(c) Notwithstanding the foregoing provisions of Section 5.3(b), in the event the testing results of the independent Third Party testing organization are not available within [*] after Dynavax's receipt of Merck's notice that the Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, failed to meet the Specifications, Dynavax shall, at Merck's request, Deliver additional Hepatitis B Surface Antigen Licensed, Vaccine or Product, as the case may be, to Merck corresponding to the amount of Hepatitis B Surface Antigen,

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Licensed Vaccine or Product, as the case may be, in dispute. Any Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, which is determined by the independent testing organization to have failed to meet the Specifications shall be destroyed or returned to Dynavax, at Dynavax's cost. If the independent testing organization determines that Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, meets the Specifications, Merck shall pay for the additional Hepatitis B Surface Antigen, Licensed Vaccine or Product, as the case may be, to the extent the Manufacturing Price for such Hepatitis B Surface Antigen has not been paid, or the price agreed to by the Parties in the case of the Licensed Vaccine or Product.

(d) The Parties agree that the sole remedy for Merck for failure of the warranty under this Section 5.3 shall be to either (i) be provided a refund of amounts previously paid, or (b) for Dynavax promptly to manufacture and Deliver a replacement quantity that meets the Specifications.

5.4 Disclaimers: The Parties intend and agree that no warranties exist beyond these stated in this Agreement. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. FURTHERMORE, EXCEPT FOR BREACH OF ITS OBLIGATIONS TO THE OTHER PARTY UNDER SECTION 4.1 OF THE LICENSE AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES, LICENSEES OR SUBLICENSEES, OFFICERS, DIRECTORS, AGENTS, REPRESENTATIVES OR EMPLOYEES FOR ANY LOST PROFITS, LOSS OF BUSINESS, LOSS OF CONTRACTS, DIMINISHED GOODWILL, DIMINISHED REPUTATION, OR CONSEQUENTIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR SPECIAL DAMAGES OF THE OTHER PARTY ARISING FROM OR IN CONNECTION WITH THIS AGREEMENT, *PROVIDED, HOWEVER,* THAT THIS SECTION 5.4 SHALL NOT LIMIT EITHER PARTY'S

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6. QUALITY CONTROL

6.1 Compliance with Specifications, cGMP, etc: Dynavax shall Manufacture Hepatitis B Surface Antigen in accordance with the Specifications. Hepatitis B Surface Antigen supplied hereunder shall be labelled in compliance with the drug listing, and Dynavax shall notify Merck and the FDA of any change to the labelling that would affect the drug listing.

6.2 Change Control: Dynavax shall provide Merck with prior written notice of, and obtain Merck's prior written consent to, any proposed changes in Specifications, subcontractors, facilities (including the Facility or Pilot Facility), equipment, Materials (including source thereof) and Manufacturing processes in accordance with the Quality Agreement, and shall bear all costs and expenses associated with such changes, including without limitation, direct costs and expenses incurred by Merck as a result of such changes. All direct costs and expenses for changes requested by Merck shall be borne by Merck. In addition, Dynavax shall at its expense, (a) provide Merck with all information required by Merck to amend the Authorizations due to the changes implemented by Dynavax, and (b) continue to supply Merck with Hepatitis B Surface Antigen approved under the existing Authorizations until such time as the changes are permitted under the applicable Authorizations.

6.3 Quality Control Testing: Dynavax shall perform quality control testing of all the batches of Hepatitis B Surface Antigen manufactured by Dynavax under this Agreement and shall Deliver only the batches which passed the quality control testing. Dynavax shall furnish Merck with signed original certificates of quality control testing for each such batch of Hepatitis B Surface Antigen. Dynavax shall complete and maintain intermediate bulk Hepatitis B Surface Antigen hold time stability to support defined hold times for bulk Hepatitis B Surface Antigen and the resulting Licensed Vaccine or Product. Dynavax shall release Hepatitis B Surface Antigen in accordance with EU Qualified Person Guidelines.

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6.4 Facilities, Audit and Inspection: Dynavax shall Manufacture Hepatitis B Surface Antigen at the Pilot Facility or Facility (once qualified), which may not be relocated without Merck's prior written consent. Merck shall be entitled, [*] with reasonable notice, to audit Dynavax's manufacturing documents and to inspect the Pilot Facility and/or Facility or both, and Dynavax shall, at its sole cost and expense, implement corrective actions mutually agreed upon by the Parties if Merck identifies and documents to Dynavax any noncompliance with cGMP in Dynavax's manufacturing process. Notwithstanding the foregoing, Merck shall have the right to conduct additional audits to the extent necessary to address specific quality problems relating to the Manufacture or in response to Regulatory Authority requirements. Dynavax shall also cause its subcontractors and suppliers to permit Merck, at reasonable intervals with appropriate notice, to audit such subcontractors and suppliers in the event Merck elects to do so, and shall cause such subcontractors and suppliers to implement corrective actions mutually agreed upon by the Parties if Merck identifies and documents any noncompliance with the cGMP with respect to the performance of Dynavax's subcontractors or suppliers. Dynavax shall advise Merck promptly of any Regulatory Authority inspections and their outcomes, or any written or oral inquiries by such Regulatory Authority. Dynavax shall provide Merck promptly with a summary of the inspection results and a copy of any responses to such inspection results.

6.5 Equipment Validation: Dynavax shall be responsible for operating and maintaining the Facility, the Pilot Facility and equipment, validating the equipment (including without limitation conducting installation, operational and performance qualification), production, cleaning, packaging, process and any other appropriate steps performed at the Facility or Pilot Facility in accordance with (a) cGMPs and (b) Dynavax's standard operating procedures.

6.6 Certificates of Analysis: Dynavax shall provide Merck with certificates of analysis related to Hepatitis B Surface Antigen for each batch released for Delivery hereunder. These certificates will document that each batch received by Merck conforms to the Specifications at the time such Hepatitis B Surface Antigen is Delivered from the Facility or Pilot Facility, as the case may be. These certificates shall include results of tests performed to meet the Specifications, the date of Manufacture, expiry date for Hepatitis B Surface Antigen as

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appropriate, and any other information to support final release of Licensed Vaccine or Product. A copy of each certificate shall be included with each batch Delivered to Merck, and one copy shall be delivered by electronic media contemporaneously to the Merck representative specified in the applicable Firm Order.

6.7 Test Methods: Dynavax shall supply Merck and any Regulatory Authority that conducts testing with analytical test methods and other testing know-how, including method validation, required to perform local testing as may be required by the Regulatory Authority in the Territory, upon request, with appropriate quantities of reference standards relating to Hepatitis B Surface Antigen, ISS 1018, and Licensed Vaccine (to the extent controlled by Dynavax) free of charge, in order to facilitate Merck's testing.

6.8 Final Release: Merck shall be responsible for the final release of Product for sale in the Territory in accordance with Merck's standard practices and the BLA. Dynavax shall provide Merck with copies of all relevant records as requested by Merck, including, but not limited to any significant Manufacturing deviations or any out-of-Specification test result, significant changes to manufacturing or testing, and copies of each batch record controlled by Dynavax with respect to Manufacturing hereunder and necessary in order for Merck to comply with its responsibilities for final release of Licensed Vaccine and/or Product. A complete listing of documents required for final release will be listed in the Quality Agreement (as defined below).

6.9 Avoidance of Cross-Contamination: Dynavax hereby confirms, as of the Effective Date, that Dynavax is not producing, packaging, labelling, warehousing, quality control testing (including in-process, release and stability testing), releasing or shipping any chemical entity classified as penicillins or other beta-lactam antibiotics such as cephalosporins or carbapenems, steroids, hormones, alkaloids, controlled substances, Live Agents, cytotoxic drug substances, pesticides, herbicides, fungicides, or other toxic non-drug substances in the Facilities. The term "*Live Agent*" means a product containing a living organism that causes infectious disease, including, but not limited to, viruses, bacteria, rickettsia, fungi, and protozoa. In the event that Dynavax intends, during the Term, to produce, package, label, warehouse, quality

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control test (including in-process, release but excluding stability testing), release or ship any chemical entity belonging to the classes of products listed above in the Facility or Pilot Facility, Dynavax shall promptly notify Merck in writing of its intention to do so in order to allow Merck to consider any potential questions of cross-contamination or regulatory requirements. In the event Merck reasonably identifies a potential problem which may result in cross-contamination with Product or Regulatory Authority requirements that would prohibit the activity, Merck shall provide Dynavax with written notice and the Parties shall meet to seek to resolve the problem in good faith; provided that, in no event shall Hepatitis B Surface Antigen Manufactured at the Pilot Facility or Facility identified in Merck's notice be Delivered to Merck after the date of the notice until such problem has been resolved to the reasonable satisfaction of both Parties.

6.10 Annual Reviews: Dynavax shall implement and perform an annual review program for the Manufacture of bulk Hepatitis B Surface Antigen mutually agreed by the Parties including, but not limited to, a review of production-related and quality control testing, as more fully described in the Quality Agreement.

6.11 Quality Agreement: No later than [*] after the Effective Date, the Parties shall negotiate in good faith and execute a quality agreement (the "**Quality Agreement**") which shall (a) supplement the terms of this Article 6, and (b) set forth in detail the quality assurance arrangements and procedures with respect to Hepatitis B Surface Antigen and the cGMPs responsibilities between the Parties.

7. DELIVERY

7.1 Dynavax shall Deliver, or arrange for Delivery of, the Hepatitis B Surface Antigen purchased by Merck hereunder in accordance with the Firm Order [*] (as the case may be, "**Deliver**" or a "**Delivery**"). Merck shall [*] for (a) [*], and (b) [*].

8. MANUFACTURING PRICE; PAYMENT PROCEDURE

8.1 Manufacturing Price: The manufacturing price of the Hepatitis B Surface Antigen shall be [*] (the "**Initial Pricing**"); and [*] (the "**Steady State Pricing**"), together with

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the Initial Pricing, the “*Manufacturing Fee*”). On an ongoing basis but not less than once per year, the Parties agree to hold good faith discussions to review ways in which [*].

8.2 Adjustment to Steady State Pricing: The Steady State Pricing shall be subject to an adjustment commencing [*] of the Major Market Launch equal to the increase in the [*]; *provided, however*, that in no event shall the annual increase be greater than [*] when compared to the previous years Steady State Price; provided further that if the increase in such index for the immediately preceding anniversary exceeds [*].

8.3 Invoice and Payment: Dynavax shall invoice Merck for each shipment of Hepatitis B Surface Antigen upon Delivery in accordance with this Section 8.3. Each Complete Invoice shall be sent via facsimile or similar electronic means, followed by an original copy forwarded via first class mail. Merck shall pay in full for each Complete Invoice within [*] from the date of Merck’s receipt of the Complete Invoice.

A “*Complete Invoice*” is an invoice that contains the following information and any other information specifically requested by Merck prior to Delivery: (a) name of Dynavax and “Remit to” wire account and address, (b) Merck’s purchase order number, (c) invoice number, (d) invoice date, (e) description of goods and services, (f) total invoice amount with miscellaneous charges listed separately and (g) payment terms consistent with the terms of this Agreement.

8.4 Taxes: To the extent that Hepatitis B Surface Antigen supplied hereunder is subject to any sales, use, value added or any other taxes, payment of said taxes, if any, is Merck’s sole responsibility; provided that Dynavax shall be liable for any and all taxes on any and all income it receives from Merck under this Agreement.

9. SECURITY OF SUPPLY

The Parties shall undertake the following arrangements to ensure continued supply of Hepatitis B Surface Antigen.

9.1 Master Cell Banks. Dynavax shall [*] (each, a “*Master Cell Bank*”, together the “*Master Cell Banks*”) [*].

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9.2 Backup Source. Following [*], in order to [*], Dynavax agrees to maintain [*] (the "*Pilot Facility*") [*].

10. TECHNOLOGY TRANSFER

10.1 Supply Failure Technology Transfer: Dynavax shall promptly notify Merck in writing of the reasons for a Supply Failure, any proposed remedial measures with regard thereto and the date such Supply Failure is expected to end. If such Supply Failure will end [*], the Parties shall continue the supply relationship. If Merck believes that the Supply Failure will not end in such period, the Parties shall submit the matter for dispute resolution pursuant to Section 12.6 of the License Agreement; provided, however, [*].

10.2 Process Technology Transfer: As soon as practicable following the Effective Date, but no later than [*] from the Effective Date, [*].

11. CUSTOMER COMPLAINTS AND RECALL

11.1 Customer Complaints: Merck shall be responsible for and take control over responding to any complaint or claim relating to the Product which is distributed and sold by Merck or its Related Parties in the Territory; provided however that when any such complaint or claim is reasonably suspected to be due to Dynavax's Manufacturing of Hepatitis B Surface Antigen, Merck shall so notify Dynavax and Dynavax shall promptly investigate its Manufacturing and report to Merck the result of such investigation, including the rectifying steps to be taken if any defect is found in the Manufacturing or the quality control, and shall implement such rectifying steps at Dynavax's sole cost and expense. In any event, Merck shall keep Dynavax informed of any complaints or claims relating to the Product that might reasonably be related to the Manufacture of the Hepatitis B Surface Antigen.

11.2 Recalls: Merck shall have the right to make decisions to recall Product in the Territory and shall promptly notify Dynavax after Merck makes such decision. In the event that a recall is caused by (a) breach of any of the representations, warranties and covenants set forth in Sections 5.1 and 5.2 of this Agreement, or (b) Dynavax's negligence or willful misconduct, Dynavax shall reimburse Merck for (i) the Manufacturing Price paid by Merck for Hepatitis B

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Surface Antigen incorporated in the recalled Product, (ii) all costs associated with shipping and distributing the recalled Product, and (iii) all expenses reasonably incurred in connection with such recall.

12. TERM AND TERMINATION

12.1 Term: This Agreement shall become effective on the Effective Date and shall continue in full force and effect for [*], unless otherwise terminated in accordance with this Agreement or the License Agreement (the "*Term*").

12.2 Termination by Either Party for Uncured Material Breach: This Agreement may be terminated by written notice given by either Party for material breach by the other Party, effective upon notice following the expiry of the cure periods described in the License Agreement, as set forth in Section 10.3.1 of the License Agreement, or if the BLA relating to the Licensed Vaccine or Product is deactivated or withdrawn by any Regulatory Authority in the US or European Market, provided that such termination shall only be effective if the deactivation or withdrawal remains in effect [*] of such notice.

12.3 Termination by Merck: This Agreement may be terminated by written notice given by Merck to Dynavax, effective upon notice following the expiry of the cure periods described below, as follows:

(a) if the License Agreement terminates for other than a breach by Merck; or

(b) if any required license (including the commercial manufacturing license issued in Germany), permit or certificate of Dynavax to Manufacture Hepatitis B Surface Antigen is not approved or not issued or is deactivated or withdrawn by any Regulatory Authority in the US or European Market and such non-approval, non-issue, deactivation or withdrawal would inevitably cause Dynavax to be unable to meet its supply obligations hereunder; provided, that such termination shall only be effective if remaining uncured [*] after receipt of such notice.

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12.4 Consequences of Certain Terminations by Merck: In the event that this Agreement is terminated by Merck in accordance with Sections 12.2 or 12.3 above, Merck shall, at its option, either (a) have the right (but not the obligation) within [*] of termination to purchase all Hepatitis B Surface Antigen already Manufactured by Dynavax pursuant to Firm Orders at the Manufacturing Price and (i) to sell the resulting Product in the Territory, and (ii) receive a technology transfer for the Hepatitis B Surface Antigen pursuant to Section 10.1; [*]; or (b) require Dynavax to purchase at the Manufacturing Price all Hepatitis B Surface Antigen inventory in Merck's possession, along with the cost of Materials reasonably incurred by Merck to further process the Hepatitis B Surface Antigen into Product. In such event, all Firm Orders shall be cancelled and Merck and Dynavax shall have no further liability with respect thereto.

12.5 Consequences of Certain Terminations by Dynavax and by Merck for Convenience: In the event that this Agreement is terminated by Dynavax in accordance with Section 12.2 above or by Merck in accordance with Section 10.2.1 of the License Agreement, Dynavax shall have the right to (a) sell to Merck (and Merck shall have the obligation to purchase) (i) all Hepatitis B Surface Antigen already Manufactured by Dynavax pursuant to Firm Orders at the Manufacturing Price and (ii) to the extent that Dynavax shall not exercise its rights pursuant to Section 10.4.3 of the License Agreement, all Materials and work-in-process then owned by Dynavax or for which Dynavax has non-cancellable commitments which cannot be diverted to Dynavax's other uses; and (b) (i) either cancel all Firm Orders or require Merck to purchase all Hepatitis B Surface Antigen to be Manufactured pursuant to Firm Orders and (ii) to the extent that Dynavax shall not exercise its rights pursuant to Section 10.4.3 of the License Agreement, all Materials and work-in-process then owned by Dynavax or for which Dynavax has non-cancellable commitments which cannot be diverted to Dynavax's other uses.

12.6 Consequences of Natural Expiration: Upon the expiration of the Term, other than for termination under Sections 12.2 or 12.3, Dynavax shall grant Merck a technology transfer for the Hepatitis B Surface Antigen pursuant to Section 10.1; [*]. [*] prior to the expiration of this Agreement, Dynavax shall provide copies of all existing Manufacturing

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Technology to Merck in order to allow Merck to commence the process of performing the technology transfer outlined in Section 10.1.

12.7 Accrued Rights: Unless otherwise agreed in this Agreement, termination of this Agreement shall not relieve the Parties of any liability or obligation which accrued under this Agreement prior to the termination. Upon the termination under Section 12.2, outstanding debts due to the other Party shall become due and payable immediately irrespective of any payment terms previously agreed upon by the Parties.

12.8 Other Remedies: Termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have under this Agreement or at law or in equity with respect to any breach of this Agreement.

13. MANUFACTURING RECORDS

13.1 All Manufacturing records (other than the Master Cell Bank and Working Cell Bank records, which shall be retained indefinitely) shall be retained by Dynavax for a period of [*]; provided that all Manufacturing records associated with validation batches shall be retained by Dynavax throughout the term of this Agreement. Dynavax shall provide Merck with complete and accurate copies of the appropriate documents for each production batch, upon Merck's request. Dynavax shall notify Merck of any intention to destroy Manufacturing records after the applicable retention period set forth above and shall afford Merck the opportunity to obtain such records. For purposes of this Section 13.1, "**Working Cell Bank**" shall mean a cell bank prepared from aliquots of a homogeneous suspension of cells obtained from culturing the Master Cell Bank.

14. INSURANCE

14.1 Dynavax shall procure and maintain, at its sole cost and expense, with a carrier rated "A-" or higher by A.M. Best, (a) comprehensive general liability and/or umbrella insurance, with coverage limits of not less than [*], and (b) property/casualty insurance on all material property owned, leased or in the possession of Dynavax, including, but not limited to the Facility and Pilot Facility, with coverage limits of not less than replacement cost. In addition

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to the foregoing, Dynavax shall maintain product liability insurance against claims arising from the Manufacture, distribution and use of Hepatitis B Surface Antigen, Licensed Vaccine or Product (to the extent provided by Dynavax to Merck herein), with coverage limits of not less than [*]. Dynavax shall maintain such policies at all times during the Term (and any extension thereof), and shall provide such coverage for no less than [*]. All Dynavax insurance required under this Section 14.1 shall name Merck as an additional insured. Dynavax shall provide Merck with certificates of insurance with respect to this Section 14.1 promptly following the Effective Date. Dynavax shall immediately notify Merck or any changes in the status of the insurance specified in this Article 14, and shall from time to time thereafter, at Merck's reasonable request, provide to Merck with a certificate of insurance attesting that such insurance remains in full force and effect. Maintenance by Dynavax of the insurance required by this Section 14.1 shall not relieve Dynavax of any responsibility for liability in excess of insurance limits or otherwise.

14.2 Merck shall procure and maintain or otherwise self-insure at the levels corresponding to those provided for Dynavax in Section 14.1, and shall provide coverage, if under a policy of insurance, for no less than [*]. Maintenance by Merck of the insurance or self-insurance required by this Section 14.2 shall not relieve Merck of any responsibility for liability in excess of insurance limits or otherwise.

15. INTEGRATION; SURVIVAL

15.1 All the following provisions of the License Agreement are hereby incorporated by reference for all purposes herein: Articles 4, 11 and 12.

15.2 The following provisions shall survive any expiration or termination of this Agreement: Articles 1, 4, 5, 6, 7, 8, 9, 10, 12, 13, 14 and 15; and Sections 2.1, 2.2, 11.4, 11.5, 11.6, 11.7, and 11.8 of this Agreement; and Articles 11 and 12 of the License Agreement. Any and all such provisions shall remain in full force and effect in accordance with their terms.

15.3 In the event of any conflicts between the terms of this Agreement and the License Agreement, the terms of this Agreement shall prevail; provided that in no event shall any term of

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this Agreement be deemed to amend or modify Article 2, Article 3, Article 5 and Article 9 of the License Agreement.

16. U.N. CONVENTION ON INTERNATIONAL SALE OF GOODS

16.1 Notwithstanding any provision contained herein to the contrary, the Parties hereby expressly agree that the U.N. Convention on International Sale of Goods shall not apply.

17. COUNTERPARTS

17.1 This Agreement may be executed in identical duplicate copies exchanged by telefacsimile transmission or by electronic mail in .pdf format with acknowledgment of receipt (other than by automated response) by the receiving Party. The Parties agree to execute two (2) identical original copies of this Agreement after exchanging signed telefacsimile/electronic versions. Each identical counterpart shall be deemed an original, but all of which together shall constitute one and the same instrument.

In WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MERCK & Co., Inc.

By: /s/ Richard T. Clark
Name: Richard T. Clark
Title: Chairman, President and Chief Executive Officer

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ Dino Dina
Name: Dino Dina, M.D.
Title: President and Chief Executive Officer

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EXHIBIT A

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[*].

[*]

	[*]	[*]	[*]
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[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
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[*]		[*]	[*]
[*]		[*]	[*]

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EXHIBIT B

Price

[*]

[*]
[*]
[*].
[*]
[*].
[*]
[*]

[*]	[*] [*]	[*]	[*] [*]	[*][*]
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[*]	[*] [*]	[*]	[*] [*]	[*][*]
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[*].

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SCHEDULE 5.1(b)

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List of Subsidiaries
Rhein Biotech GmbH

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on (a) Form S-8 (File No. 333-113220) of Dynavax Technologies Corporation pertaining to the 1997 Equity Incentive Plan, the 2004 Stock Incentive Plan and the 2004 Employee Stock Purchase Plan of Dynavax Technologies Corporation, (b) Form S-3 (File Nos. 333-145836 and 333-147455) of Dynavax Technologies Corporation and in the related Prospectuses, and (c) Form S-3/A (File Nos. 333-139664, 333-134688 and 333-147455) of Dynavax Technologies Corporation and in the related Prospectuses of our reports dated March 13, 2008, with respect to the consolidated financial statements of Dynavax Technologies Corporation and the effectiveness of internal control over financial reporting of Dynavax Technologies Corporation, included in this Annual Report (Form 10-K) for the year ended December 31, 2007.

/s/ ERNST & YOUNG LLP

San Francisco, California
March 13, 2008

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

CERTIFICATIONS

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

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

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

Date: March 17, 2008

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

CERTIFICATIONS

I, Deborah A. Smeltzer, certify that:

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

By: /s/ DEBORAH A. SMELTZER

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

Date: March 17, 2008

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

I, Dino Dina, M.D., hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

(i) The Annual Report of the Company on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and

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

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

Date: March 17, 2008

