# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Form 10-K

(Mark One)

Large accelerated filer  $\square$ 

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

For the fiscal year ended December 31, 2013

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

For the transition period from

Commission file number: 001-34207

# **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:

Common Stock, \$0.001 Par Value Preferred Shares Purchase Rights Name of Each Exchange on Which Registered:

The NASDAQ Stock Market LLC

Smaller reporting company  $\square$ 

# Securities Registered Pursuant to Section 12(g) of the Act:

None

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

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  $\Box$  No  $\boxtimes$ 

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  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T ( $\S$ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files). Yes  $\boxtimes$  No  $\square$ 

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):

(Do not check if a smaller reporting company)

Accelerated filer ⊠

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

Non-accelerated filer □

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 28, 2013 as reported on the NASDAQ Capital Market, was approximately \$105,519,624. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2014, the registrant had outstanding 262,855,958 shares of common stock.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2014 Annual Meeting of Stockholders are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

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**SIGNATURES** 

#### 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 ability to successfully develop and achieve regulatory approval for HEPLISAV-B™, our business strategy, our intellectual property position, our product development efforts, our ability to commercialize our product candidates, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and 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," or "intend," 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 1A—Risk Factors" and "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 ("we," "our," "us," "Dynavax" or the "Company"), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor ("TLR") biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B<sup>TM</sup> (also known as "HEPLISAV"), an investigational adult hepatitis B vaccine in Phase 3 clinical development. HEPLISAV-B combines our proprietary TLR 9 agonist adjuvant and hepatitis B surface antigen ("HBsAg") to elicit an immune response after two doses. In the spring of 2014 we expect to initiate a Phase 3 study of HEPLISAV-B compared with Engerix-B® in adults 18-70 years of age in order to provide a sufficiently-sized safety database for the U.S. Food and Drug Administration ("FDA") to complete its review of Dynavax's biologics license application ("BLA").

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline ("GSK"), our asthma therapeutic program partnered with AstraZeneca AB ("AstraZeneca"), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

# THE COMPANY AND BACKGROUND

We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000. Dynavax Technologies Corporation is listed on the NASDAQ Capital Market under the ticker symbol "DVAX."

Our principal executive offices are located at 2929 Seventh Street, Suite 100, Berkeley, California, 94710-2753. Our telephone number is (510) 848-5100. We make available, free of charge on our website located at www.dynavax.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission. Our code of conduct, audit committee charter, nominating and corporate governance committee charter, compensation committee charter and audit committee complaint procedures are also posted on our website and are each available in print to any stockholder upon request by writing to: 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. The contents of our website are not incorporated by reference into this report.

# PROPRIETARY TECHNOLOGY

#### **Toll-like Receptors**

TLRs, structures located on different immune cell types, are activated by the binding of certain pathogens and other ligands and their activity is essential to generation of innate immunity. By either activating or inhibiting specific TLRs, it is possible to selectively modulate elements of the innate immune response on the cellular level to address dysfunction associated with both excessive immune activity (autoimmunity) and suboptimal immune function. Dynavax research has resulted in the identification of proprietary synthetic oligonucleotides (short segments of the deoxyribonucleic acid ("DNA"), that selectively activate or inhibit specific TLRs, allowing their use in a range of immune-mediated therapeutic and preventative applications.

#### **TLR Agonists**

TLR agonists bind to receptors on specific cell types activating a cascade that enhances the ability of the immune system to identify and fight disease. TLR agonists work by enhancing or reprogramming the innate immune response.

Currently, our development programs focus on TLR 9 agonists. Since TLR 9 is found exclusively in a specialized subset of dendritic and B cells, TLR 9 agonists do not cause a generalized activation of the immune system but rather redirect the response of only those T-cells involved in a given disease. We have developed a number of proprietary TLR 9 agonist compositions and formulations that make use of the different ways in which the innate immune system responds to stimulation.

TLR 9 agonists can be administered therapeutically to stimulate immune responses for the treatment of cancer and infectious diseases. They can also be combined with vaccine antigens to enhance the specific immune response to the vaccine. TLR 9 agonists help generate memory T Helper ("Th") 1 cells that can stimulate the immune system to induce long-lasting effects. We use this approach in HEPLISAV-B by combining the TLR 9 agonist adjuvant with HBsAg. This combination induces a highly specific Th1 immune response and durable levels of protective antibodies. HEPLISAV-B has been shown to provide significantly greater seroprotection in persons with reduced immune function due to disease processes (diabetes, chronic kidney disease), overall health (smoking, obesity), and advanced age.

TLR 9 agonists can also be used alone to modify the course of the viral and respiratory disease by modulating the immune system. TLR 9 agonists have the potential to suppress the Th2 inflammatory response to modify the underlying cause of allergic inflammation.

For several programs, we have used our advanced proprietary knowledge to design modifications of the molecular structure of CPG oligonucleotide TLR 9 agonists to significantly increase their versatility and potency. These second-generation TLR 9 agonists stimulate specific immune responses, including potent interferon-alpha induction.

#### **TLR Inhibitors**

TLR inhibitors are short DNA sequences that selectively block the abnormal activation of TLRs associated with autoimmune and inflammatory diseases. In animal studies, our TLR inhibitors have demonstrated broad potential to reduce such inflammatory responses characteristic of multiple autoimmune diseases, including lupus, inflammatory skin disorders and rheumatoid arthritis.

# DEVELOPMENT PROGRAMS

Our pipeline of product candidates includes the following:

| Product Candidate | <b>Description</b>    | Clinical Indication(s)               | <b>Phase</b> | Partnership/Funding |
|-------------------|-----------------------|--------------------------------------|--------------|---------------------|
| HEPLISAV-B        | TLR 9 agonist & HBsAg | Hepatitis B prevention               | Phase 3      | Dynavax             |
| DV1179            | TLR 7/9 inhibitor     | Autoimmune and inflammatory diseases | Phase 1      | GSK                 |
| AZD1419           | TLR 9 agonist         | Asthma                               | Phase 1      | AstraZeneca         |
| SD-101            | TLR 9 agonist         | Cancer immunotherapy                 | Phase 1      | Dynavax             |
| DV230             | TLR 9 agonist         | Adjuvant technology                  | Preclinical  | NIAID               |

# **HEPLISAV-B Hepatitis B Vaccine**

HEPLISAV-B is an investigational adult hepatitis B vaccine that combines our proprietary TLR agonist, 1018, with HBsAg manufactured in our Dynavax facility in Düsseldorf, Germany ("Rhein" or "Dynavax Europe"). In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than currently-licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV-B.

On February 25, 2013, we received a complete response letter ("CRL") from the FDA indicating that it would not approve HEPLISAV-B for the indication proposed in our BLA. Following extensive discussions with the FDA, we finalized the design of an additional clinical study of HEPLISAV-B that is intended to provide a sufficiently-sized safety database for the FDA to complete its review of our BLA and make a final determination regarding the safety and immunogenicity of the product. The planned study will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV-B compared with Engerix-B in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV-B subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV-B subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of the study will be: (1) to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate ("SPR") induced by HEPLISAV-B versus Engerix-B in subjects with type 2 diabetes mellitus. HEPLISAV-B subjects will be evaluated for safety for one year following the second dose, all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee and safety will be monitored by a Data and Safety Monitoring Board. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015. We estimate the external costs of the study to be in the range of \$50-55 million.

We submitted our Marketing Authorization Application ("MAA") for HEPLISAV-B to the European Medicines Agency's ("EMA") in July of 2012. In late 2012 we received the Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use of the EMA regarding our MAA, which related primarily to the suitability of different patient populations, the safety database size, and Good Manufacturing Practices ("GMP") and Good Clinical Practices ("GCP") matters. In the early summer of 2013, EMA added to the list of questions, resetting the clock for our response. EMA also inspected several study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in Chronic Kidney Disease ("CKD") patients that is part of the EMA application but not the U.S. application. In the fourth quarter of 2013, we submitted our responses to the 120-Day Questions. The Day 180 List of Outstanding Issues ("LOI") provided by the EMA in February 2014 indicated that, based primarily on the GCP inspection findings, HBV-17 was not acceptable and because some of the findings were related to the Dynavax's overall systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. On February 18, 2014 we announced the withdrawal of the MAA for HEPLISAV-B under review by the EMA. We withdrew the application, in part, because the required time frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data. The Phase 3 study to be initiated in the U.S. in 2014 is expected to provide additional data to support the safety of HEPLISAV-B.

#### **Commercial Opportunity**

Hepatitis B infection can become a chronic disease that, in some patients, leads to cirrhosis of the liver, hepatocellular carcinoma and death. There is no cure for chronic hepatitis B infection, and disease prevention through effective vaccines is critical to reducing the spread of the disease. Available hepatitis B vaccines for adults have several limitations, including:

- · Slow onset of protection—the current regimen for adults is usually 3 doses given over 6 months to provide seroprotection of approximately 30%, 75% and 90% after the first, second and third doses respectively;
- · Poor protection in populations that are hypo-responders—current vaccines provide a lower seroprotection rate for persons over 40 years of age including males, the obese, smokers, diabetics and immunocompromised persons, such as end-stage renal disease patients; and
- $\cdot$  Poor compliance—in certain settings only 30% of people receive all 3 doses.

HEPLISAV-B is designed to address the limitations of currently-licensed vaccines by providing higher and earlier protection with fewer doses.

We estimate the total worldwide market for adult hepatitis B vaccines approximates \$680 million annually. This market is primarily comprised of GSK's Engerix-B and Twinrix® as well as Merck & Co.'s ("Merck") Recombivax-HB®. Key market segments consisting of persons considered to be at high risk for hepatitis B virus ("HBV") infection include chronic kidney disease patients, people with multiple sexual partners or injection drug use, healthcare workers and first responders, travelers, chronic liver disease patients and, in the U.S., people with diabetes mellitus (type 1 and type 2).

We intend to focus our initial commercialization efforts on the U.S. market. Currently, the U.S. market for adult hepatitis B vaccines is approximately \$270 million annually. In late 2012 the Advisory Committee on Immunization Practices ("ACIP") expanded its recommendation for adults who should be vaccinated against hepatitis B to include people with diabetes mellitus (type 1 and type 2). According to the Centers for Disease Control and Prevention ("CDC") there are 20 million adults diagnosed with diabetes and another 1.5 million new cases diagnosed each year. This population represents a significant increase in the number of adults recommended for vaccination against hepatitis B in the U.S.

### **DV1179 TLR Inhibitor for Autoimmune and Inflammatory Diseases**

DV1179 is a novel inhibitor of TLR 7 and TLR 9 that is being evaluated as a therapeutic for autoimmune and inflammatory diseases, under a worldwide strategic alliance with GSK. In late 2011, we initiated a proof-of-mechanism clinical trial of DV1179 in systemic lupus erythematosus ("SLE") patients. This indication was selected because SLE is characterized by spontaneous lymphoproliferation, expansion of autoreactive B and T cells, and production of polyclonal autoantibodies against numerous nuclear antigens. TLR 7 and TLR 9 have been implicated in the chronic inflammatory response in this disease. GSK has an exclusive option to obtain a license to this program following completion of this trial expected in the second half of 2014.

# **AZD1419 TLR Agonist for Asthma Therapy**

We are developing AZD1419, a novel candidate drug for asthma, under our collaboration agreement with AstraZeneca. AZD1419 is a proprietary second-generation TLR agonist and represents a new disease-modifying approach to the treatment of allergic respiratory diseases. AZD1419 is designed to change the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms by converting the response from one primarily mediated by type-2 helper T cells (Th2) to type-1 helper T cells (Th1).

In October 2013 we initiated dosing in a Phase 1 study to assess the safety of AZD1419. In the first part of the study, up to approximately 45 healthy subjects will receive inhaled doses of AZD1419 or a placebo in single and multiple ascending doses, followed by up to approximately 24 patients with mild asthma in the second (Phase 1b) part of the study. Safety data from the first part of the study is expected in mid-2014.

#### **SD-101 for Immunotherapy of Cancer**

SD-101 is a proprietary second-generation TLR 9 agonist that was designed to stimulate a specific immune response, including potent interferon-alpha induction. This product candidate has been evaluated in two phase 1 studies to assess its safety and tolerability and is currently being tested in an investigator-sponsored study in patients with relapsed lymphoma after allogeneic bone marrow transplant.

# **DV230 Adjuvant Technology**

We have developed a new adjuvant platform, DV230, with funding received from the National Institute of Allergy and Infectious Diseases ("NIAID"). Oligonucleotide TLR 9 agonists are strong activators of innate immunity and highly effective adjuvants. However, in situations where an extraordinarily rapid development of protective antibody titers is desired, it is beneficial to enhance the adjuvant function further by means of a nanoparticle formulation. The nanoparticle form of molecule DV230, covalently linked to the highly cross-linked sucrose polymer Ficoll, has demonstrated significant potency advantages in enhancing the magnitude and durability of the primary immune response in preclinical models of anthrax infection. We are currently evaluating this technology for a range of potential applications.

#### PARTNERSHIPS AND OTHER FUNDING AGREEMENTS

Our objective is to discover novel therapies based on our proprietary technologies and develop a diversified pipeline of product candidates to build a product-based commercial business. To reach this objective, an important part of our strategy is to establish partnerships with leading pharmaceutical and biotechnology companies and enter into funding agreements. Our pharmaceutical partners provide valuable resources, expertise and abilities that allow us to further advance the development of our product candidate programs. We also have funding agreements with U.S. government institutions.

### GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize TLR inhibitors. Under the terms of the arrangement, we agreed to conduct research and early clinical development in up to four programs: the Lead TLR 7/9 program, a Follow-On TLR 7/9 program, and up to two other TLR programs. In 2011 we began development of a TLR 8 program as one of the two additional programs under the collaboration. GSK subsequently returned all rights to this program to us. In December 2013, we amended our agreement with GSK to extend the research term until conclusion of the ongoing phase 1 study of DV1179. In addition, the exclusivity provisions of the agreement were modified, giving us rights to immediately begin preclinical and clinical research on inhibitors of TLR 7 and 9 (other than DV1179) for oncology indications.

We are currently conducting a Phase 1 clinical trial in the Lead TLR 7/9 program with DV1179 in systemic lupus erythematosus patients. The Company is not currently performing any activities on the Follow-On TLR 7/9 program. GSK has not yet chosen to initiate development of the remaining program under the agreement.

GSK can exercise its exclusive option to license each program. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. If GSK exercises their option on the Lead TLR 7/9 program, then we are eligible to receive payments of up to approximately \$125 million, comprised of contingent option exercise payments and additional payments based on GSK's achievement of certain development, regulatory and commercial objectives.

We are also eligible to receive up to \$60 million if aggregate worldwide annual net sales milestones are achieved and tiered royalties ranging from the mid–single digit to mid-teens on sales of any products originating from the collaboration. We have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of \$10 million in 2008. In 2011, we earned and recognized \$12 million in substantive development milestone payments related to the initiation of Phase I and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients. In 2011, we earned and recognized \$3 million in substantive development milestone payments related to the initiation of development of the TLR 8 program.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause upon prior written notice within a specified window of time dependent upon the stage of clinical development of the programs.

#### AstraZeneca AB

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR 9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The research term of this agreement was extended through July 2010.

In October 2011, we amended our agreement with AstraZeneca to provide that we would conduct initial clinical development of AZD1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a. A Phase 1 study was initiated in 2013 and is expected to conclude in 2015.

In March, 2014 we announced a \$5.4 million milestone payment and amendment of our AstraZeneca agreement to transfer responsibility for all clinical development to AstraZeneca following conclusion of the ongoing Phase 1 clinical trial of AZD1419. If AstraZeneca continues development of AZD1419, we will receive milestones upon initiation of the first Phase 2 trial and the first Phase 3 trial. Additionally, we are eligible to receive potential future development payments and, upon commercialization, we are eligible to receive royalties based on product sales of any products originating from the collaboration. We have the option to co-promote in the U.S. products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

# **National Institutes of Health and Other Funding**

In September 2008, we were awarded a \$17 million contract to develop our advanced TLR 9 agonist technology as vaccine adjuvants. This five-year contract was awarded by the National Institute of Health's ("NIH") NIAID and supports adjuvant development for biodefense vaccines, including anthrax as well as other diseases. NIAID is funding 100% of the total \$17 million cost of our program under Contract No. HHSN272200800038C. The NIH may terminate performance of work under the contract if the contracting officer determines that a termination is in the government's interest or if we default in performing and fail to cure after notice. In 2013, the NIAID agreed to extend the contract term by one year to continue the research efforts as defined in the original contract. The activities under this agreement are expected to conclude in the second half of 2014.

During 2010, we were awarded a grant from the NIAID to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against hepatitis B. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program, from which we were awarded \$0.2 million in 2013, \$0.3 million in 2012, \$0.3 million in 2011 and \$0.5 million in 2010. We were also awarded a \$0.6 million grant in 2010 from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus.

During 2011, 2012 and 2013, we were awarded grants from the NIH to fund research in the amounts of \$0.6 million, \$1.0 million, and \$0.2 million, respectively. The 2012 grant included \$0.4 to fund research in screening for inhibitors of TLR 8 for treatment of rheumatoid arthritis and \$0.6 million to fund development of TLR 8 inhibitors.

# INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and knowhow, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. In addition to seeking patent protection in the U.S., we generally file patent applications in Australia, Canada, Japan, Western European countries and additional foreign countries on a selective basis to further protect the inventions that we or our partners consider important to the development of our business. We also rely on trade secrets and contracts to protect our proprietary information.

As of December 31, 2013, our intellectual property portfolio included 28 issued U.S. patents, over 200 issued or granted foreign patents and over 50 additional pending U.S. and foreign patent applications claiming compositions and formulations of TLR agonist and inhibitors, their methods of use or processes for their manufacture. We also have exclusive licenses under two agreements to several patents and applications owned by the Regents of the University of California.

We have an issued U.S. patent covering the TLR agonist contained in our HEPLISAV-B investigational vaccine that will expire in 2018, and have correspondingly issued patents in several major European and other countries. We own or have an exclusive license to U.S. and foreign patent applications pending for each of our other product candidates and/or their uses. At present, it is not known or determinable whether patents will issue from any of these applications or what the specific expiration dates would be for any patents that do issue.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued in the U.S. are effective for:

- the longer of 17 years from the issue date or 20 years from the earliest effective filing date, if the patent application was filed prior to June 8, 1995; and
- · 20 years from the earliest effective filing date, if the patent application was filed on or after June 8, 1995.

In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is 20 years from the earliest effective filing date. Our patent estate, based on patents existing now and expected by us to issue based on pending applications, will expire on dates ranging from 2017 to 2033.

The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents.

Because patent applications in the U.S. and many foreign jurisdictions typically are not published until 18 months after filing and publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in each of our issued patents or pending patent applications or that we were the first to invent and/or the first to file for protection of the inventions set forth in these patent applications. The U.S. Patent and Trademark Office ("PTO") may declare interference proceedings to determine the priority of inventions with respect to our patent applications and those of other parties or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed.

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. ("Pfizer"), as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions 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. 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. Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering recombinant HBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur owns or has exclusive licenses to patents covering HBsAg. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S.. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK, their licensors or the Institut Pasteur may bring claims against us.

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. 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. For example, Pfizer has issued U.S. and foreign patent claims as well as patent claims pending with the PTO and foreign patent offices that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of TLR agonist other than with respect to HEPLISAV-B, for which we have a license. Litigation or any other proceedings, such as patent interferences, could result in substantial costs to and diversion of effort by us, 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. We may not prevail of these actions or proceedings, if any.

In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or our licensors.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our policy is to require each of our commercial partners, 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. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

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, share a portion of fees from third party partnerships up to a specified amount and pay low single-digit royalties on net sales resulting from successful products originating from the licensed technologies. To date, we have paid the University of California a total of \$1.9 million in license fees and shared third party partnership fees and milestone payments under these agreements. We estimate the total potential milestone payments payable for each such product will total approximately \$3.1 million, not including royalties. 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 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.

#### **COMPETITION**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Our products and development programs target a number of areas including viral, respiratory, autoimmune and inflammatory diseases. There are many commercially available products for the treatment of these diseases. Many companies and institutions are making substantial investments in developing additional products to treat these diseases that could compete directly or indirectly with our products under development.

HEPLISAV-B, a two-dose hepatitis B vaccine, if approved and commercialized, will compete directly with conventional three-dose marketed vaccines produced by GSK and Merck, among others. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in the European Union and U.S.. In addition, HEPLISAV-B will compete against a multivalent vaccine produced by GSK that simultaneously protect against hepatitis B and hepatitis A.

Our therapy for autoimmune and inflammatory diseases, DV1179, if developed, approved and commercialized will compete with key biologic therapies from companies such as F. Hoffman-La Roche Ltd. and its subsidiary Genentech, Inc. ("Roche/Genentech"), Amgen Inc., Biogen Idec, AbbVie and GSK. In addition, our product would compete with generic drugs commonly used to treat autoimmune diseases, including corticosteroids, non-steroidal anti-inflammatory drugs, antimalarials and immunosuppressive agents. Other companies, such as AstraZeneca and its subsidiary MedImmune, LLC, Roche/Genentech, Idera Pharmaceuticals, Pfizer and UCB S.A. and its partner Immunomedics, Inc., are developing anti-IFN-alpha-antibodies, B-cell targeted antibodies, immunosuppressants, and other TLR inhibitors that may compete directly with our product candidate.

Our asthma therapy, AZD1419, if developed, approved and commercialized, will compete indirectly with existing asthma therapies, such as inhaled beta-agonists, corticosteroids, leukotriene inhibitors and IgE monoclonal antibodies, including those marketed by Merck, Roche/Genentech, Novartis International AG, AstraZeneca and GSK. In addition, directly competing products may be in development by Sanofi-Aventis and Idera Pharmaceuticals.

Our cancer immunotherapy, SD101, if developed, approved and commercialized will compete with a range of biological therapies being used or studied to treat blood cancer including:

- · Monoclonal antibody therapy, including radioimmunotherapy
- · Interferons and interleukins
- · Donor lymphocyte infusion
- · Reduced-intensity allogeneic stem cell transplantation
- · Therapeutic cancer vaccines

Approved and late-stage investigational cancer immunotherapeutics are marketed or being developed by numerous companies, including Bristol-Myers Squibb, Roche/Genentech, Merck, GSK, Gilead, and Pharmacyclics.

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 we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through 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

In the U.S., pharmaceutical and biological products are subject to rigorous review and approval by the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations. In Europe, under the centralized procedure, a company submits a single application to the European Medicines Agency. The steps ordinarily required by the regulatory authorities before a new drug or biological product may be marketed in the U.S. and in most other countries include but are not limited to the following:

- · completion of preclinical laboratory tests, preclinical studies and formulation studies;
- · submission to the regulatory authority of a clinical application 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;
- · demonstration of the consistent manufacturing of drug substance and drug product;
- the submission of a new drug application to the regulatory authority; and
- · regulatory review and approval of the application before any commercial marketing, sale or shipment of the drug.

If applicable requirements are not met, regulatory authorities may issue fines, require that a company recall its products, seize products, require that a company totally or partially suspend the production of its products, refuse to approve a marketing application, pursue criminal prosecution and/or revoke previously granted marketing authorizations.

To secure regulatory authority approval, we must submit extensive non-clinical and clinical data, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and other supporting information to the regulatory authority. 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. In addition, the development of the drug substance and drug product may require manufacturing modifications to ensure future regulatory acceptance. The approval process takes many years, requires the expenditures of substantial resources, and involves post-marketing surveillance.

Delays experienced during the 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 a 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.

The FDA or foreign regulatory agency 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. Following approval, we may be required to conduct additional post-marketing studies. The regulatory authority may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing.

Non-clinical studies involve laboratory evaluation of product characteristics or animal studies to assess the initial efficacy and safety of the product. The FDA or other foreign regulatory agency, under its good laboratory practices regulations, regulates certain non-clinical studies. 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. Violations of these regulations can, in some cases, lead to invalidation of those studies, requiring these studies to be repeated. The results of these tests, together with manufacturing information and analytical data, are submitted to the regulatory authority as part of a clinical application, which must be approved by the regulatory authority before we can commence clinical investigations in humans.

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 GCP regulations under protocols submitted to applicable regulatory authorities as part of the clinical application. GCP regulations mandate comprehensive documentation for the clinical protocol, record keeping, training, and facilities including computers. Quality assurance and inspections are designed to ensure that these GCP standards are achieved. Additionally, each clinical trial must be approved and conducted under the auspices of an Institutional Review Board ("IRB") or Independent Ethics Committee and with patient informed consent. The IRB will consider, among other matters, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial.

The stages of the regulatory process include clinical trials in three sequential phases that may overlap. 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 regulatory approval of the product candidate.

We and all of our contract manufacturers are required to comply with the applicable FDA or foreign regulatory agency current GMP regulations. Manufacturers of biologics also must comply with a regulatory authority'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. Before granting product approval, the regulatory authority must determine that our or our third party contractor's manufacturing facilities meet GMP requirements before we can use them in the commercial manufacture of our products. In addition, our facilities are subject to periodic inspections by the regulatory authority for continued compliance with GMP requirements during clinical development as well as following product approval. Adverse experiences with the product must be reported to the FDA or foreign regulatory agency and could result in the imposition of market restriction through labeling changes or in product removal.

If our products are approved for sale, we will be subject to further regulatory requirements under federal and state provisions such as federal "sunshine" laws, anti-kickback laws, false claims laws and state law equivalents of those and other regulations. We are also subject to various federal, state, local and foreign 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.

#### **MANUFACTURING**

We rely on our facility in Dusseldorf, Germany and third parties to perform the multiple processes involved in manufacturing our product candidates, including the manufacturing of TLR agonist and inhibitors, antigens, the combination of the TLR agonist and the antigens, and the formulation, fill and finish of these products. The process for manufacturing oligonucleotides is well-established and uses commercially available equipment and raw materials. We have relied on a limited number of suppliers to produce products for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of TLR agonist and inhibitors ourselves for development purposes. We currently manufacture the HBsAg for HEPLISAV-B at our Dynavax Europe facility.

# RESEARCH AND DEVELOPMENT

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were \$50.9 million, \$49.1 million and \$51.3 million for the years ended December 31, 2013, 2012 and 2011, respectively.

# **ENVIRONMENT**

We have made, and will continue to make, expenditures for environmental compliance and protection. We do not expect that expenditures for compliance with environmental laws will have a material effect on our capital expenditures or results of operations in the future.

# **EMPLOYEES**

As of December 31, 2013, we had 151 full-time employees, including 21 Ph.D.s, 1 M.D. and 17 others with advanced degrees. Of the 151 employees, 122 were dedicated to research and development activities. None of our employees is subject to a collective bargaining agreement and we believe our relations with our employees are good.

# ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K contains forward-looking statements concerning our future products, product candidates, timing of development activities, regulatory strategies, intellectual property position, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

#### **Risks Related to our Business**

The success of our product candidates, in particular HEPLISAV-B, depends on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approvals for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, can take many years and require the expenditure of substantial resources and we are unable to predict the timing of when regulatory approval may be received, if ever, in any jurisdiction.

For our lead product, HEPLISAV-B, our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program is satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party clinical research organizations; the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our 2013 CRL, HEPLISAV-B was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. While we are undertaking a study intended to obtain additional safety data information to the FDA, there can be no assurance that this additional clinical study will support approval, or that the data will provide acceptable immunogenicity data for patients with diabetes. The FDA also requested additional data from our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities in our

In addition, we recently announced our withdrawal of our Marketing Authorization Application for approval to the EMA based in part upon our determination that in the required timeframe for response under the MAA procedure we would not be able to collect the necessary clinical data in a timely manner to respond to the EMA's list of outstanding issues regarding the safety database. While we expect to begin shortly an additional HEPLISAV clinical trial, HBV-23, that is intended to provide a safety database sufficient to support licensure, there can be no assurance that we can timely initiate or complete such study in a timely manner, nor that our safety database will be sufficient or acceptable to support MAA approval. Moreover, our withdrawal means that additional questions raised by the EMA in the continuing review process were not completed and there can be no assurance that we would be able to respond sufficiently to satisfy the other outstanding questions from the EMA with respect to our MAA.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

Failure to receive approval or significant delay in being able to provide the safety and manufacturing information required for approval of our BLA for HEPLISAV-B would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet current GMP requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable current GMP regulations. Manufacturers of biological products must also comply with the FDA's general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product.

The FDA may require more clinical trials for our product candidate than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests 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;
- · potentially limit the markets for those products;
- · adversely affect our ability to enter into collaborations or 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. Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We are undertaking an additional trial of HEPLISAV-B and expect to commence clinical trials for our other product candidates in the future. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain institutional review board, or IRB, or other regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

Failure by us or our clinical research organizations ("CROs") to conduct a clinical study to GCP standards could result in disqualification of the clinical trial from consideration in support of approval of a potential product.

We are responsible for conducting our clinical trials consistent with GCP standards and for oversight of our vendors to ensure that they comply with such standards. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with GCP. To the extent that they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may also unfavorably impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of participants.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the trial design;
- · deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- · deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;

- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fail to conform to acceptable standards;
- · our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- · our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- · our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- · our liability to obtain regulatory approval to conduct a clinical trial;
- · lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- · our inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board ("DSMB"), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

# HEPLISAV-B and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to either 1018 or other TLR agonists may require us to reduce the scope of or discontinue our operations.

HEPLISAV-B incorporates 1018, a TLR 9 agonist CPG oligonucleotide, and most of our research and development programs use similar oligonucleotides. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain oligonucleotides, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

# We have no commercialization experience, and the time and resources to develop sales, marketing and distribution capabilities for HEPLISAV-B are significant. If we fail to achieve and sustain commercial success for HEPLISAV-B, either directly or with a partner, our business would be harmed.

Our lead product candidate, HEPLISAV-B, if approved, would require us to establish sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services. These efforts will require resources and time and we may not be able to enter into these arrangements on acceptable terms. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV-B to patients with diabetes, a group recently recommended by the CDC and ACIP to receive hepatitis B vaccination. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV-B may significantly impact our ability to achieve commercial success in this potential patient population.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing HEPLISAV-B, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV-B, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, certain revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our product candidates. We rely on a limited number of suppliers to produce the oligonucleotide we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including 1018, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, 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 or commercialization efforts.

We have relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing supplier for 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce 1018 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-B. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations. As part of the review of our BLA filing for HEPLISAV-B, the FDA requested additional data regarding our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities and there can be no assurance that our responses will be sufficient to meet the FDA requirements for GMP manufacturing.

In addition, we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit, delay or disrupt the commercialization of HEPLISAV-B and could result in significant expense. Moreover, depending on the level of market acceptance of HEPLISAV-B, if approved, we may not have the capacity in our existing facility to meet all of our future commercial supply needs. Our current manufacturing capacity could supply up to approximately 2 million doses of hepatitis B surface antigen annually, and our ability to expand Düsseldorf manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity plans, we may experience a shortage in supply of HEPLISAV-B, which could have a material adverse effect on the success of HEPLISAV-B. Likewise, in the event that HEPLISAV-B is not approved, we would have to consider other alternatives for the facility in Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, and time-consuming.

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

We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. 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/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. 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. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. 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.

If, as a result of their inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

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 commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

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.

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

We may introduce certain of our product candidates, including HEPLISAV-B, in various markets outside the U.S.. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. 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;
- · obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- · legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- · regional and geopolitical risks.

We have withdrawn our MAA in Europe and we may not be able to timely initiate our planned clinical trial or provide sufficient data from such trial or respond to other comments to our previously filed MAA sufficient to obtain foreign regulatory approvals in Europe in a reasonable time period or at all. Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. 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.

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 commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- · the indication for which the product is approved and its approved labeling;
- · the presence of other competing approved therapies;
- $\cdot$   $\;$  the potential advantages of the product over existing and future treatment methods;

- the relative convenience and ease of administration of the product;
- · the strength of our sales, marketing and distribution support;
- · the price and cost-effectiveness of the product; and
- · sufficient third-party reimbursement.

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 achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

We face uncertainty regarding 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, in particular for HEPLISAV-B where existing products are already marketed. 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, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. 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 uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. 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 are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV-B, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

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, modified or terminated. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

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, in particular with respect to the commercialization of HEPLISAV-B, if approved. Failure to obtain a collaborative relationship for HEPLISAV-B, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product, and our recent withdrawal of our MAA increases the risk that we may be unable to enter into a collaborative relationship prior to regulatory approval. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- · our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- · our shortage of capital resources may impact the willingness of companies to collaborate with us;

- · our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- · we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- · our partners may not devote sufficient capital or resources towards our product candidates; and
- · our partners may not comply with applicable government regulatory requirements.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant 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 or to successfully transition terminated collaborative agreements, 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.

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 prevent or treat infectious and inflammatory diseases. For example, if it is approved in the future, HEPLISAV-B will compete in the U.S. with established hepatitis B vaccines marketed by Merck and GSK and outside the U.S. with vaccines from those companies and several additional established pharmaceutical companies. 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.

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. Although certain of our employees have commercialization experience, as a company we currently have limited sales, marketing and distribution capabilities. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we are successful in advancing HEPLISAV-B through the development stage towards commercialization, we will need to expand our organization, including adding marketing and sales capabilities or contracting with third parties to provide these capabilities for us. As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud laws of the jurisdictions in which we conduct our business, we may be subject to significant liability.

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. If we obtain approval for and commercialize a vaccine or other product, our interactions with physicians and others in a position to prescribe or purchase our products will be subject to a legal regime designed to prevent healthcare fraud and abuse. Relevant U.S. laws include:

- the Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- · federal false claims laws which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- · laws that require transparency regarding financial arrangements with health care professionals, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act ("PPACA") and state laws; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third-party payer, including commercial insurers.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the healthcare fraud laws provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

In the U.S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information.

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to criminal and/or civil sanctions, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U.S. or foreign laws.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to health care fraud abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

# The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.

We depend on our senior executive officers, as well as key scientific and other personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer. We currently have no key person insurance on any of our employees.

# 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 clinical trial liability and umbrella insurance coverage for our clinical trials. 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 are involved in legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations.

Two class action complaints brought by purported stockholders and one purported stockholder derivative complaint have been brought against us. Any negative outcome from such lawsuits could result in payments of monetary damages or fines, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in these cases, and defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages or fines not covered by insurance, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

# 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 believe 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.

#### Risks Related to our Finances and Capital Requirements

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$502.2 million as of December 31, 2013. To date, our revenue has resulted from collaboration agreements, government and private agency grants and services and license fees from our customers, including the customers of Rhein. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and our addition of infrastructure and operations to support further development and regulatory approval of HEPLISAV-R

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV-B can be successfully developed, financed or commercialized in a timely manner based on our current plans. The 2013 CRL from the FDA for HEPLISAV-B means that our efforts to achieve product revenues are delayed significantly and there can be no assurance that we will be able to achieve approval or generate meaningful sales without significant additional resources. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales 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, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms.

If we are unable to generate significant revenues or achieve profitability, we will require substantial additional capital to continue development of our product candidates and if our most advanced candidate, HEPLISAV-B, is approved, to commence sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV-B, we will need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

- · development, manufacturing and, if approved, commercialization of our product candidates, particularly HEPLISAV-B;
- · various human clinical trials for our product candidates; and
- · protection of our intellectual property.

We currently estimate that we have sufficient resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as well as anticipated revenues and funding from existing agreements.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

#### **Risks Related to our Intellectual Property**

We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements 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 obtain and 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 or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In addition, we must make timely payments or meet diligence obligations to maintain any such licenses in effect. In the absence of a current license, 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.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge 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 ownership, scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. From time to time 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.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of recombinant HBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of recombinant HBsAg. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK or their respective licensors or the Institut Pasteur may bring claims against us.

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-B or any similar product candidate, 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. 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 patent claims, as well as patent claims pending with the PTO and foreign patent offices, that may be asserted against our TLR agonist products and our TLR inhibitor 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 to commercialize one or more of our formulations other than with respect to HEPLISAV-B, for which we have a license. A license for other uses 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 U.S. 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 U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the U.S., 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 may 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.

#### Risks Related to an Investment in our Common Stock

#### 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 or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and communications from the FDA or other regulatory agencies;
- · 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 establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- · changes in government regulations, general economic conditions or industry announcements;
- · issuance of new or changed securities analysts' reports or recommendations;
- · actual or anticipated fluctuations in our quarterly financial and operating results;
- · our ability to maintain continued listing on the NASDAQ markets or similar exchanges; and
- the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. We are currently the target of such securities litigation, resulting from the decline in our common stock following the disclosure in 2013 that the FDA would not approve HEPLISAV-B for sale without a significant additional clinical study. We may in the future be the target of additional such litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

The anti-takeover provisions of our certificate of incorporation, our bylaws, Delaware law and our share purchase rights plan 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;
- $\cdot$  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.

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain 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 three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

# We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in 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 registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, 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.

# Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2013, we had 262,796,285 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

In addition, we have filed shelf registration statements on Form S-3 under the Securities Act of 1933, as amended, to register securities that we may choose to issue in the future and on Form S-8 to register the shares of our common stock reserved for issuance under our stock option plans.

# ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

# ITEM 2. PROPERTIES

As of December 31, 2013, we leased approximately 55,200 square feet of laboratory and office space in Berkeley, California under agreements expiring in June 2018. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.

# ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations.

On June 18, 2013, the first of two substantially similar securities class action complaints was filed in the U.S. District Court for the Northern District of California against the Company and certain of its former executive officers. The second was filed on June 26, 2013. On August 22, 2013, these two complaints and all related actions that subsequently may be filed in, or transferred to, the District Court were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On September 27, 2013, the Court appointed a lead plaintiff and lead counsel. On November 12, 2013, the Lead Plaintiff in the In re Dynavax Technologies Securities Litigation filed his Consolidated Class Action Complaint ("Complaint"). The Complaint alleges that between April 26, 2012 and June 10, 2013, the Company and certain current and former officers and directors violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with statements related to our product candidate, HEPLISAV. The Complaint seeks unspecified damages, interest, attorneys' fees, and other costs. On January 10, 2014, the Company filed a motion to dismiss the Complaint. The hearing on the motion is set for May 2, 2014.

Additionally, on July 3, 2013, a purported stockholder derivative complaint was filed in the Superior Court of California for the County of Alameda against certain of our former and current directors. On August 9, 2013, a substantially similar purported stockholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The derivative complaint alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that certain of our current and former executive officers and directors caused or allowed for the dissemination of materially false and misleading statements regarding our product, HEPLISAV-B. Plaintiff is seeking unspecified monetary damages, including restitution from defendants and attorneys' fees and costs, and other relief.

On August 21, 2013, pursuant to a stipulation between the parties, the State Court stayed the state derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On October 17, 2013, pursuant to a stipulation between the parties, the federal court stayed the federal derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation.

The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously.

# ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

# 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 Capital Market under the ticker 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 intra-day sale prices per share of our common stock.

|                | Common Stock<br>Price |     |      |  |  |
|----------------|-----------------------|-----|------|--|--|
|                | <br>Pı                | ice |      |  |  |
|                | High                  |     | Low  |  |  |
| 2013           |                       |     | ,    |  |  |
| First Quarter  | \$<br>3.39            | \$  | 1.74 |  |  |
| Second Quarter | \$<br>2.68            | \$  | 0.98 |  |  |
| Third Quarter  | \$<br>1.46            | \$  | 1.02 |  |  |
| Fourth Quarter | \$<br>2.05            | \$  | 1.10 |  |  |
| 2012           |                       |     |      |  |  |
| First Quarter  | \$<br>5.08            | \$  | 3.24 |  |  |
| Second Quarter | \$<br>5.34            | \$  | 3.33 |  |  |
| Third Quarter  | \$<br>4.99            | \$  | 3.48 |  |  |
| Fourth Quarter | \$<br>5.10            | \$  | 2.22 |  |  |

As of February 28, 2014, there were approximately 84 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 14,200 as the number of record holders excludes shares held in "street name" through brokers.

# Dividends

We have never paid 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.

# **Recent Sales of Unregistered Securities**

None.

# **Issuer Purchases of Equity Securities**

|                     |                        |                     |                               | (d)                           |
|---------------------|------------------------|---------------------|-------------------------------|-------------------------------|
|                     |                        |                     | (c)                           | Maximum Number                |
|                     |                        |                     | <b>Total Number of Shares</b> | (or Approximate Dollar Value) |
|                     | (a)                    |                     | (or Units) Purchased as       | of Shares (or Units) that     |
|                     | <b>Total Number of</b> |                     |                               |                               |
|                     | Shares                 | (b)                 | Part of Publicly              | May Yet Be Purchased          |
|                     | (or Units)             |                     |                               |                               |
|                     | Purchased(1)           | Average Price Paid  | <b>Announced Plans or</b>     | <b>Under the Plans or</b>     |
| Period              | (In thousands)         | per Share (or Unit) | Programs                      | Programs                      |
| October 1, 2013 to  |                        |                     |                               |                               |
| October 31, 2013    | -                      | \$ -                | -                             | -                             |
| November 1, 2013 to |                        |                     |                               |                               |
| November 30, 2013   | -                      | -                   | -                             | -                             |
| December 1, 2013 to |                        |                     |                               |                               |
| December 31, 2013   | -                      | -                   | -                             | -                             |
| Total               | -                      | <u>-</u>            |                               |                               |

<sup>(1)</sup> During the 3 months ended December 31, 2013, no securities were purchased by the Company.

#### 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, 2013, 2012 and 2011 and the Consolidated Balance Sheets Data as of December 31, 2013 and 2012 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, 2010 and 2009 and the Consolidated Balance Sheets Data as of December 31, 2010 and 2009 are derived from audited 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.

|  | Year Ended December 31, |          |    |             |       |               |      |          |    |          |
|--|-------------------------|----------|----|-------------|-------|---------------|------|----------|----|----------|
|  |                         | 2013     |    | 2012        |       | 2011          |      | 2010     |    | 2009     |
|  |                         |          |    | (In thousan | ds, e | except per sl | ıare | data)    |    |          |
| Consolidated Statements of Operations Data:                              |                         |          |    |             |       |               |      |          |    |          |
| Total revenues   | \$                      | 11,251   | \$ | 9,714       | \$    | 21,614        | \$   | 23,950   | \$ | 40,318   |
| Operating expenses:  |                         |          |    |             |       |               |      |          |    |          |
| Research and development   |                         | 50,870   |    | 49,146      |       | 51,322        |      | 53,680   |    | 38,708   |
| General and administrative   |                         | 25,943   |    | 28,164      |       | 17,570        |      | 16,879   |    | 15,745   |
| Unoccupied facility expense  |                         | 926      |    | -           |       | -             |      | -        |    | -        |
| Amortization of intangible assets  |                         |          |    |             |       | 299           |      | 980      |    | 980      |
| Total operating expenses   |                         | 77,739   |    | 77,310      |       | 69,191        |      | 71,539   |    | 55,433   |
| Loss from operations   |                         | (66,488) |    | (67,596)    |       | (47,577)      |      | (47,589) |    | (15,115) |
| Other income (expense):  |                         |          |    |             |       |               |      |          |    |          |
| Interest income  |                         | 116      |    | 291         |       | 103           |      | 85       |    | 178      |
| Interest expense   |                         | -        |    | (2,351)     |       | (1,957)       |      | (1,654)  |    | (124)    |
| Other income (expense)(1)  |                         | (348)    |    | (293)       |       | 834           |      | (8,150)  |    | (66)     |
| Net loss   |                         | (66,720) |    | (69,949)    |       | (48,597)      |      | (57,308) |    | (15,127) |
| Consideration paid in excess of carrying value of the noncontrolling     |                         |          |    |             |       |               |      |          |    |          |
| interest in Symphony Dynamo, Inc. ("SDI")(2)                             |                         | -        |    | -           |       | -             |      | -        |    | (19,671) |
| Add: Losses attributable to noncontrolling interest in SDI               |                         | -        |    | -           |       | -             |      | -        |    | 4,233    |
| Net loss attributable to Dynavax   |                         | (66,720) |    | (69,949)    |       | (48,597)      |      | (57,308) |    | (30,565) |
| Preferred stock deemed dividend(3)                                       |                         | (8,469)  |    | -           |       | -             |      | -        |    | -        |
| Net loss allocable to Dynavax common stockholders                        | \$                      | (75,189) | \$ | (69,949)    | \$    | (48,597)      | \$   | (57,308) | \$ | (30,565) |
| Basic and diluted net loss per share allocable to Dynavax common         |                         |          |    |             |       |               |      |          |    |          |
| stockholders   | \$                      | (0.38)   | \$ | (0.41)      | \$    | (0.39)        | \$   | (0.69)   | \$ | (0.76)   |
| Shares used to compute basic and diluted net loss per share allocable to |                         |          |    |             |       |               |      |          |    |          |
| Dynavax common stockholders  |                         | 196,275  |    | 170,469     |       | 125,101       |      | 82,463   |    | 40,350   |

<sup>(1)</sup> Includes the impact of the anti-dilution provision associated with the common stock and warrants issued to Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, "Symphony") and the change in fair value of the Symphony-related long-term contingent and warrant liabilities for the year ended December 31, 2010. See Note 8 to the Consolidated Financial Statements.

<sup>(2)</sup> Represents the consideration paid in excess of the carrying value of the noncontrolling interest in SDI that was treated as a deemed dividend for purposes of reporting earnings per share, increasing net loss per share for the year ended December 31, 2009. See Note 8 to the Consolidated Financial Statements.

<sup>(3)</sup> Deemed dividend related to beneficial conversion feature of convertible preferred stock. The fair value of the common stock into which the Series B Preferred Stock is convertible exceeded the allocated purchase price of the Series B Preferred Stock by \$8.5 million on the date of issuance, resulting in a deemed dividend. The Company recognized the deemed dividend as a one-time, non-cash, deemed dividend to the holders of Series B Preferred Stock on the date of issuance, which is the date the stock first became convertible.

|  | December 31,  |    |           |       |           |    |           |    |           |
|--|---------------|----|-----------|-------|-----------|----|-----------|----|-----------|
|  | <br>2013      |    | 2012      |       | 2011      |    | 2010      |    | 2009      |
|  |               |    |           | (In t | housands) |    |           |    |           |
| Consolidated Balance Sheets Data:                |               |    |           |       |           |    |           |    |           |
| Cash, cash equivalents and marketable securities | \$<br>189,376 | \$ | 125,130   | \$    | 113,961   | \$ | 72,154    | \$ | 36,720    |
| Working capital                                  | 176,186       |    | 109,173   |       | 97,399    |    | 60,598    |    | 24,583    |
| Total assets                                     | 204,622       |    | 139,752   |       | 134,102   |    | 84,249    |    | 50,470    |
| Note payable to Symphony Dynamo Holdings LLC(1)  | -             |    | -         |       | 12,810    |    | 10,939    |    | 9,342     |
| Accumulated deficit                              | (502,211)     |    | (435,491) |       | (365,542) |    | (316,945) |    | (259,637) |
| Total Dynavax stockholders' equity               | 186,294       |    | 114,826   |       | 99,880    |    | 52,111    |    | 6,376     |

<sup>(1)</sup> The note payable to Symphony Dynamo Holdings LLC ("Holdings") was paid in cash on December 31, 2012.

# 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, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as 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 ("we," "our," "us," "Dynavax" or the "Company"), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor ("TLR") biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B<sup>TM</sup> (also known as "HEPLISAV"), an investigational adult hepatitis B vaccine in Phase 3 clinical development. HEPLISAV-B combines our proprietary TLR 9 agonist adjuvant and hepatitis B surface antigen ("HBsAg") to elicit an immune response after two doses. In the spring of 2014 we expect to initiate a Phase 3 study of HEPLISAV-B compared with Engerix-B® in adults 18-70 years of age in order to provide a sufficiently-sized safety database for the U.S. Food and Drug Administration ("FDA") to complete its review of Dynavax's Biologics License Application ("BLA").

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline ("GSK"), our asthma therapeutic program partnered with AstraZeneca AB ("AstraZeneca"), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of \$502.2 million at December 31, 2013. These losses have resulted principally from costs incurred in connection with research and development activities, compensation and other related personnel costs and general corporate expenses. Research and development activities include costs of outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. General corporate expenses include outside services such as accounting, consulting, business development, investor relations, insurance services and legal costs. Our operating results may fluctuate substantially from period to period principally as a result of the timing of preclinical activities and other activities related to clinical trials for our drug candidates.

As of December 31, 2013, we had \$189.4 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and revenues from collaboration agreements to fund our operations. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

# **Recent Developments**

On February 25, 2013, we received a complete response letter ("CRL") from the FDA indicating that it would not approve HEPLISAV-B for the indication proposed in our BLA. Following extensive discussions with the FDA, we finalized the design of an additional clinical study of HEPLISAV-B that is intended to provide a sufficiently-sized safety database for the FDA to complete its review of our BLA and make a final determination regarding the safety and immunogenicity of the product. The planned study will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV-B compared with Engerix-B in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV-B subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV-B subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of the study will be: (1) to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate ("SPR") induced by HEPLISAV-B versus Engerix-B in subjects with type 2 diabetes mellitus. All HEPLISAV-B subjects will be evaluated for safety for one year following the second dose, all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee and safety will be monitored by a Data and Safety Monitoring Board. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015. We estimate the external costs of the study to be in the range of \$50-55 million.

We submitted our Marketing Authorization Application ("MAA") for HEPLISAV-B to the European Medicines Agency's ("EMA") in July of 2012. In late 2012 we received the Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use of the EMA regarding our MAA, which related primarily to the suitability of different patient populations, the safety database size, and Good Manufacturing Practices ("GMP") and Good Clinical Practices ("GCP") matters. In the early summer of 2013, EMA added to the list of questions, resetting the clock for our response. EMA also inspected several study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in CKD patients that is part of the EMA application but not the U.S. application. In the fourth quarter of 2013, we submitted our responses to the 120-Day Questions. The Day 180 List of Outstanding Issues ("LOI") provided by the EMA in February 2014 indicated that, based primarily on the GCP inspection findings, HBV-17 was not acceptable and because some of the findings were related to the Dynavax's overall systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. On February 18, 2014 we announced the withdrawal of the MAA for HEPLISAV-B under review by the EMA. We withdrew the application, in part, because the required time frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data. The Phase 3 study to be initiated in the U.S. in 2014 is expected to provide additional data to support the safety of HEPLISAV-B.

# **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 ("GAAP"). 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, assumptions and judgments described below that have the greatest potential impact on our consolidated financial statements, including those related to revenue recognition, research and development activities and stock-based compensation. 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. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially 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 consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. 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 collectability is reasonably assured.

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. 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.

Under the milestone method, contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are 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.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt and when the other revenue recognition criteria have been satisfied.

Revenues from manufacturing services 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.

#### 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. 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. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

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, 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, successful enrollment of patients, completion of portions of the clinical trial or similar conditions. 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 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. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2013.

# **Stock-Based Compensation**

Stock-based compensation expense for stock options and other stock awards is estimated at the grant date based on the award's fair value-based measurement and is recognized on a straight-line basis over the award's vesting period, assuming appropriate forfeiture rates. Our determination of the fair value-based measurement of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value-based measurement of stock options granted in the future. Changes in the fair value-based measurement of stock awards could materially impact our operating results.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value-based measurement of our stock options. The Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value-based measurement of stock options, including the option's expected term and the price volatility of the underlying stock. Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the quarter of revision, as well as in the following quarters.

# **Results of Operations**

#### Revenues

Revenues consist of amounts earned from collaborations, grants and services and license fees. Collaboration revenue includes amounts recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Service and license fees include revenues related to 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, 2013, 2012 and 2011 (in thousands, except for percentages):

|                             |           |             |           |          |                 | Increa       | ase   |  |
|-----------------------------|-----------|-------------|-----------|----------|-----------------|--------------|-------|--|
|                             |           |             |           | Incre    | ease            | (Decrease)   |       |  |
|                             |           |             |           | (Decreas | (Decrease) from |              | n     |  |
|                             | Year E    | inded Decem | ber 31,   | 2012 to  | 2013            | 2011 to 2012 |       |  |
| Revenues:                   | 2013      | 2012        | 2011      | \$       | %               | \$           | %     |  |
| Collaboration revenue       | \$ 4,929  | \$ 4,610    | \$ 17,190 | \$ 319   | 7%              | \$(12,580)   | (73)% |  |
| Grant revenue               | 5,138     | 3,939       | 3,110     | 1,199    | 30%             | 829          | 27%   |  |
| Service and license revenue | 1,184     | 1,165       | 1,314     | 19       | 2%              | (149)        | (11)% |  |
| Total revenues              | \$ 11,251 | \$ 9,714    | \$ 21,614 | \$ 1,537 | 16%             | \$ (11,900)  | (55)% |  |

#### 2013 versus 2012

Total revenues for the year ended December 31, 2013, increased by \$1.5 million, or 16%, as compared to the same period in 2012 principally due to an increase in grant revenue. Grant revenue for the year ended December 31, 2013, increased by \$1.2 million from the same period in 2012 primarily due to an increase in revenue recognized from our National Institute of Health's National Institute of Allergy and Infectious Diseases ("NIAID") contract for adjuvant development and other programs funded by grants.

#### 2012 versus 2011

Total revenues for the year ended December 31, 2012, decreased by \$11.9 million, or 55%, as compared to the same period in 2011 primarily due to a reduction in collaboration revenue. Collaboration revenue for the year ended December 31, 2012, included \$3.2 million earned from our partnership with AstraZeneca for work on asthma therapies, compared to \$0.8 million earned for the year ended December 31, 2011. Additionally, total collaboration revenue for the year ended December 31, 2011, included recognition of \$15 million from GSK for milestones earned in 2011. Grant revenue for the year ended December 31, 2012, increased by \$0.8 million from the same period in 2011 primarily due to an increase in revenue recognized from our NIAID contract related to adjuvant development.

# Research and Development

Research and development expense consists primarily of compensation and related personnel costs, which include benefits, recruitment, travel and supply costs, outside services, allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the years ended December 31, 2013, 2012 and 2011, approximately 73%, 73% and 79%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV-B. The remainder of our research and development expense results primarily from earlier-stage programs. The following is a summary of our research and development expense (in thousands, except for percentages):

|  |           |                         |           |          |          | Incre        | ase   |  |
|--|-----------|-------------------------|-----------|----------|----------|--------------|-------|--|
|  |           |                         |           | Incr     | ease     | (Decre       | ase)  |  |
|  |           |                         |           | (Decrea  | se) from | froi         | n     |  |
|  | Year E    | Year Ended December 31, |           |          | o 2013   | 2011 to 2012 |       |  |
| Research and Development:                | 2013      | 2012                    | 2011      | \$       | %        | \$           | %     |  |
| Compensation and related personnel costs | \$ 20,649 | \$ 21,134               | \$ 19,106 | \$ (485) | (2)%     | \$ 2,028     | 11%   |  |
| Outside services                         | 20,247    | 19,371                  | 24,811    | 876      | 5%       | (5,440)      | (22)% |  |
| Facility costs                           | 5,746     | 5,127                   | 5,302     | 619      | 12%      | (175)        | (3)%  |  |
| Non-cash stock-based compensation        | 4,228     | 3,514                   | 2,103     | 714      | 20%      | 1,411        | 67%   |  |
| Total research and development           | \$ 50,870 | \$ 49,146               | \$ 51,322 | \$ 1,724 | 4%       | \$ (2,176)   | (4)%  |  |

#### 2013 versus 2012

Research and development expense for the year ended December 31, 2013, increased by \$1.7 million, or 4%, as compared to 2012. Outside services increased by \$0.9 million compared to 2012 primarily due to additional development work related to our adjuvant studies and collaboration with AstraZeneca. Facility costs increased by \$0.6 million compared to 2012 primarily due to repairs and maintenance of our manufacturing facility and depreciation on recently purchased manufacturing equipment. Non-cash stock-based compensation expense increased by \$0.7 million due to accelerated vesting of stock options and modifications of stock options related to management continuity and severance agreements. Compensation and related personnel costs decreased by \$0.5 million primarily due to a decrease in employee headcount.

#### 2012 versus 2011

Research and development expense for the year ended December 31, 2012, decreased by \$2.2 million, or 4%, as compared to 2011. The decrease in costs was primarily due to the decline in outside services during 2012 as compared to 2011 due to lower HEPLISAV-B clinical trial expenses, partially offset by an increase in compensation and related personnel costs, including non-cash stock-based compensation, from an increase in employee headcount and related expense incurred for option grants.

#### General and Administrative

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

The following is a summary of our general and administrative expenses (in thousands, except for percentages):

|  | Year Ended December 31, |           | ber 31,   | Increa<br>(Decrease<br>2012 to | ) from | Increase<br>(Decrease) from<br>2011 to 2012 |      |  |
|--|-------------------------|-----------|-----------|--------------------------------|--------|---|------|--|
| General and Administrative:              | 2013                    | 2012      | 2011      | \$                             | %      | \$  | %    |  |
| Compensation and related personnel costs | \$ 10,521               | \$ 9,468  | \$ 7,398  | \$ 1,053                       | 11%    | \$ 2,070                                    | 28%  |  |
| Outside services                         | 4,319                   | 8,730     | 4,548     | (4,411)                        | (51)%  | 4,182                                       | 92%  |  |
| Legal costs                              | 2,361                   | 2,437     | 1,894     | (76)                           | (3)%   | 543   | 29%  |  |
| Facility costs                           | 630                     | 604       | 644       | 26                             | 4%     | (40)  | (6)% |  |
| Non-cash stock-based compensation        | 8,112                   | 6,925     | 3,086     | 1,187                          | 17%    | 3,839                                       | 124% |  |
| Total general and administrative         | \$ 25,943               | \$ 28,164 | \$ 17,570 | \$ (2,221)                     | (8)%   | \$ 10,594                                   | 60%  |  |

#### 2013 versus 2012

General and administrative expenses for the year ended December 31, 2013, decreased by \$2.2 million, or 8%, compared to the same period in 2012. Outside services expense decreased \$4.4 million due to reduced marketing expenses. Compensation costs and non-cash stock-based compensation increased due to severance expense and other one-time compensation costs as well as accelerated vesting of stock options related to the transition of our former Chief Executive Officer and certain other employees and executive officers.

### 2012 versus 2011

General and administrative expenses for the year ended December 31, 2012, increased by \$10.6 million, or 60%, compared to the same period in 2011. This increase is primarily due to higher legal and outside costs, including consulting costs for corporate development activities and market research for HEPLISAV-B. Compensation costs and non-cash stock-based compensation increased due to growth in the number of administrative employees to support the organization and an amended management continuity and severance agreement with one of our executive officers.

# Amortization of Intangible Assets

Intangible assets consisted of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and were amortized over five years from the date of acquisition through the second quarter of 2011. Amortization of intangible assets was \$0.3 million for the year ended December 31, 2011.

### Interest Income, Interest Expense and Other Income (Expense)

Interest income is reported net of amortization of premiums and discounts on marketable securities, realized gains and losses on investments, and fees related to investment portfolio management. Interest expense in 2012 was related to the \$15 million note payable held by Symphony Dynamo Holdings LLC ("Holdings"), which was paid in cash on December 31, 2012. Other expense includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment.

The following is a summary of our interest income, interest expense and other income (expense) (in thousands, except for percentages):

|                        |             |             |            | Incre        | ase    | Incre         | ease   |
|------------------------|-------------|-------------|------------|--------------|--------|---------------|--------|
|                        |             |             |            | (Decrease    | ,      | (Decreas      | ,      |
|                        | <br>Year    | Ended Decem | ber 31,    | 2012 to      | 2013   | <br>2011 to   | 2012   |
|                        | 2013        | 2012        | 2011       | \$           | %      | <br>\$        | %      |
| Interest income        | \$<br>116   | \$ 291      | \$ 103     | \$ (175)     | (60)%  | \$<br>188     | 183%   |
| Interest expense       | \$<br>-     | \$ (2,351)  | \$ (1,957) | \$ (2,351)   | (100)% | \$<br>394     | 20%    |
| Other income (expense) | \$<br>(348) | \$ (293)    | \$ 834     | <b>\$</b> 55 | 19%    | \$<br>(1,127) | (135)% |

Interest income for the year ended December 31, 2013, decreased by \$0.2 million, or 60%, compared to the same period in 2012 due to lower average marketable securities balance. Interest income for the year ended December 31, 2012, increased by \$0.2 million, or 183%, compared to the same period in 2011 due to higher investment balances primarily as a result of our May 2012 common stock offering which resulted in net proceeds of approximately \$69.6 million.

Interest expense for the year ended December 31, 2013 decreased compared to the same period in 2012 due to the interest recorded for the note payable to Holdings which was repaid in cash on December 31, 2012. Interest expense for the year ended December 31, 2012 increased over the same period in 2012 due to the accretion of interest expense related to the note payable to Holdings.

Other income (expense) for the year ended December 31, 2013 increased by 19%, compared to the same period in 2012 due to losses on foreign currency transactions in 2013 related to fluctuations in the value of the Euro compared to the U.S. dollar. Other income (expense) for the year ended December 31, 2012 decreased by \$1.1 million, or 135%, compared to the same period in 2011 due to losses on foreign currency transactions in 2012 related to fluctuations in the value of the Euro compared to the U.S. dollar and the recognition of a one-time gain of \$0.8 million for the change in fair value of the long-term contingent and warrant liabilities to Holdings in 2011.

# **Liquidity and Capital Resources**

As of December 31, 2013, we had \$189.4 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities and revenues from collaboration agreements to fund our operations. Our funds are currently invested in short-term money market funds, U.S. government agency securities and U.S. treasury securities.

On October 30, 2013, we sold 79,570,000 shares of our common stock and 43,430 shares of the Company's Series B Convertible Preferred Stock ("Series B"), resulting in aggregate net proceeds to us of \$125.1 million after deducting commissions and offering expenses.

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV") under which we may offer and sell our common stock having aggregate sales proceeds of up to \$50 million from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of December 31, 2013.

During the year ended December 31, 2013, we used \$58.7 million of cash for our operations and had a net loss of \$66.7 million, of which \$15.5 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and unoccupied facility expense. By comparison, during the year ended December 31, 2012, we used \$43.8 million of cash for our operations with a net loss of \$69.9 million, of which \$15.1 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and non-cash interest on borrowings. Cash used in our operations during 2013 increased by \$14.9 million, totaling \$58.7 million for the year ended December 31, 2013 compared to \$43.8 million for the same period in 2012. The increase was primarily due to a \$9.1 million change in accounts receivable related to a decrease in payments received from our collaborations with GSK and AstraZeneca in the prior year and an increase in stock based compensation of \$1.9 million related to employee severance arrangements and awards for non-employees.

During the year ended December 31, 2013, we used \$51.4 million of cash in investing activities compared to \$39.7 million for the year ended December 31, 2012. Cash provided by investing activities during 2013 included \$49.7 million of net purchases of marketable securities versus \$36.8 million of net purchases of marketable securities during 2012. Cash used in investing activities decreased an additional \$1.3 million compared to the prior year due to purchases of property and equipment which totaled \$1.6 million and \$2.9 million in 2013 and 2012, respectively.

During the year ended December 31, 2013, cash provided by financing activities increased by \$66.4 million, totaling \$125.4 million, compared to \$59.0 million for the year ended December 31, 2012. Cash provided by financing activities in 2013 included the sale of 79,570,000 shares of common stock and 43,430 shares of Series B Convertible Preferred Stock in separate underwritten public offerings for net proceeds of \$125.1 million. Cash provided by financing activities for the year ended December 31, 2012 included net proceeds of \$69.6 million from a public stock offering of common stock. These proceeds were partially offset by our \$15.0 million repayment of the note payable to Holdings on December 31, 2012. Additionally, proceeds from stock option and warrant exercises for the year ended December 31, 2013 decreased \$1.8 million as compared to the same period in 2012.

During the year ended December 31, 2012, we used \$43.8 million of cash for our operations and had a net loss of \$69.9 million, of which \$15.1 million consisted of non-cash charges such as depreciation and amortization, non-cash interest expense related to our long-term note payable to Holdings and stock based compensation. By comparison, during the year ended December 31, 2011, we used \$47.1 million of cash, and had a net loss of \$48.6 million, of which \$9.0 million consisted of non-cash charges such as depreciation and amortization, non-cash interest expense related to our long-term note payable to Holdings and stock based compensation. Cash used in operating activities for the year ended December 31, 2012, decreased by \$3.3 million compared to cash used for year ended December 31, 2011, due primarily to a decrease in accounts receivable in 2012 related to payments received from our collaborations with GSK and AstraZeneca.

During the year ended December 31, 2012, we used \$39.7 million of cash in investing activities which was a \$5.1 million increase compared to \$34.6 million used during the year ended December 31, 2011. Cash used in investing activities during the year ended December 31, 2012, primarily related to \$36.8 million of cash used for net purchases of marketable securities compared to \$33.5 million in the prior year, a \$3.3 million increase. Cash used in investing activities increased an additional \$1.8 million compared to the prior year due to purchases of property and equipment which totaled \$2.9 million and \$1.1 million in 2012 and 2011, respectively.

During the year ended December 31, 2012, cash provided by financing activities was \$59.0 million compared to \$91.4 million for the same period in 2011. Cash provided for the year ended December 31, 2012 included net proceeds of \$69.6 million from a public stock offering as well as proceeds from stock option and warrant exercises of \$4.1 million. These proceeds were partially offset by our \$15 million repayment of our note payable to Holdings on December 31, 2012. By comparison, during the year ended December 31, 2011, we completed a public offering which resulted in aggregate net proceeds of \$64.5 million, and raised additional funding from Aspire Capital totaling \$26.7 million.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of December 31, 2013 and anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

## **Contractual Obligations**

The following summarizes our significant contractual obligations at December 31, 2013 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

| Contractual Obligations:                           | ,  | Total  | 2  | 2014  | 201 | 5-2016 | 201 | 7-2018 | 19 and<br>reafter |
|--|----|--------|----|-------|-----|--------|-----|--------|-------------------|
| Future minimum payments under our operating leases | \$ | 13,080 | \$ | 2,233 | \$  | 4,615  | \$  | 3,733  | \$<br>2,499       |
| Total  | \$ | 13,080 | \$ | 2,233 | \$  | 4,615  | \$  | 3,733  | \$<br>2,499       |

We lease our facilities in Berkeley, California (the "Berkeley Lease"), and Düsseldorf, Germany (the "Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of \$0.9 million, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for the Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of December 31, 2013 and is collateralized by a certificate of deposit for \$0.4 million which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20 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 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of approximately 0.2 million Euros. The letter of credit remained outstanding through December 31, 2013 and is collateralized by a certificate of deposit for 0.2 million Euros which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012.

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. Also, 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, royalties on net sales of products originating from the licensed technologies or other payments contingent upon the occurrence of an event that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of December 31, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$4.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

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 certain products, if any, originating from the licensed technologies.

## **Off-balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC and accordingly, no such arrangements are likely to have a current or future effect on our financial position.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### **Quantitative and Qualitative Disclosure About Market Risk**

#### **Interest Rate Risk**

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The primary objective of our investment activities is to preserve principal and, secondarily, to maximize 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 short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. We do not have derivative financial instruments in our investment portfolio. To assess our risk, we calculate that if interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the pro forma change in fair value of our net unrealized loss on investments would be \$2.1 million or \$2.6 million, respectively.

Due to the short duration and conservative nature of our cash equivalents and marketable securities, as well as our intention to hold the investments to maturity, 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 with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2013 was \$0.1 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2013, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California March 10, 2014

## CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

|   |          | Decem     | ber 3 | 81,       |
|---|----------|-----------|-------|-----------|
|   | _        | 2013      |       | 2012      |
| Assets  | _        |           |       |           |
| Current assets:   |          |           |       |           |
| Cash and cash equivalents   | \$       | 23,122    | \$    | 7,599     |
| Marketable securities available-for-sale  |          | 166,254   |       | 117,531   |
| Accounts receivable   |          | 1,627     |       | 1,005     |
| Prepaid expenses and other current assets   |          | 1,375     |       | 2,052     |
| Total current assets  | _        | 192,378   |       | 128,187   |
| Property and equipment, net   |          | 8,706     |       | 7,965     |
| Goodwill  |          | 2,579     |       | 2,475     |
| Restricted cash   |          | 662       |       | 652       |
| Other assets  |          | 297       |       | 473       |
| Total assets  | \$       | 204,622   | \$    | 139,752   |
| Liabilities and stockholders' equity  |          |           |       |           |
| Current liabilities:  |          |           |       |           |
| Accounts payable  | \$       | 1,901     | \$    | 2,166     |
| Accrued liabilities   |          | 8,166     |       | 10,063    |
| Deferred revenues   |          | 6,125     |       | 6,785     |
| Total current liabilities   |          | 16,192    |       | 19,014    |
| Deferred revenues, net of current portion   |          | 1,173     |       | 5,283     |
| Other long-term liabilities   |          | 963       |       | 629       |
| Total liabilities   |          | 18,328    |       | 24,926    |
| Commitments and contingencies (Note 9)  |          |           |       |           |
| Stockholders' equity:   |          |           |       |           |
| Preferred stock: \$0.001 par value  |          |           |       |           |
| Authorized: 5,000 shares; Issued and outstanding:   |          | -         |       | -         |
| Series B Convertible Preferred Stock — 43 shares at December 31, 2013 and zero shares at December 31, 2012  |          | _         |       | _         |
| Common stock: \$0.001 par value; 350,000 and 250,000 shares authorized at December 31, 2013 and 2012,       |          |           |       |           |
| respectively; 262,796 and 182,792 shares issued and outstanding at December 31, 2013 and 2012, respectively |          | 263       |       | 183       |
| Additional paid-in capital  |          | 688,390   |       | 550,729   |
| Total accumulated other comprehensive loss  |          | (148)     |       | (595)     |
| Accumulated deficit   |          | (502,211) |       | (435,491) |
| Total stockholders' equity  |          | 186,294   |       | 114,826   |
| Total liabilities and stockholders' equity  | \$       | 204,622   | \$    | 139,752   |
| Total Industrial State of Country   | <u> </u> |           | Ψ     | 100,702   |

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

|   | Year Ended December 31, |          |       |          |    |          |
|---|-------------------------|----------|-------|----------|----|----------|
|   |                         | 2013     | 2012  |          |    | 2011     |
| Revenues:   |                         |          |       |          |    |          |
| Collaboration revenue   | \$                      | 4,929    | \$    | 4,610    | \$ | 17,190   |
| Grant revenue   |                         | 5,138    |       | 3,939    |    | 3,110    |
| Service and license revenue   |                         | 1,184    |       | 1,165    |    | 1,314    |
| Total revenues  |                         | 11,251   | · · · | 9,714    |    | 21,614   |
| Operating expenses:   |                         |          |       |          |    |          |
| Research and development  |                         | 50,870   |       | 49,146   |    | 51,322   |
| General and administrative  |                         | 25,943   |       | 28,164   |    | 17,570   |
| Unoccupied facility expense   |                         | 926      |       | -        |    | -        |
| Amortization of intangible assets   |                         | -        |       | -        |    | 299      |
| Total operating expenses  |                         | 77,739   |       | 77,310   |    | 69,191   |
| Loss from operations  |                         | (66,488) |       | (67,596) |    | (47,577) |
| Other income (expense):   |                         |          |       |          |    |          |
| Interest income   |                         | 116      |       | 291      |    | 103      |
| Interest expense  |                         | -        |       | (2,351)  |    | (1,957)  |
| Other income (expense)  |                         | (348)    |       | (293)    |    | 834      |
| Net loss  |                         | (66,720) | · · · | (69,949) |    | (48,597) |
| Preferred stock deemed dividend   |                         | (8,469)  |       | -        |    | -        |
| Net loss allocable to common stockholders   | \$                      | (75,189) | \$    | (69,949) | \$ | (48,597) |
| Net loss per share allocable to common stockholders - basic and diluted   | \$                      | (0.38)   | \$    | (0.41)   | \$ | (0.39)   |
| Weighted average shares outstanding used to compute basic and diluted net loss per share allocable to common stockholders |                         | 196,275  |       | 170,469  |    | 125,101  |

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

|  | Year Ended December 31, |      |          |    |          |  |
|--|-------------------------|------|----------|----|----------|--|
|  | <br>2013                | 2012 |          |    | 2011     |  |
| Net loss   | \$<br>(66,720)          | \$   | (69,949) | \$ | (48,597) |  |
| Other comprehensive income (loss):                                 |                         |      |          |    |          |  |
| Unrealized (loss) gain on marketable securities available-for-sale | (76)                    |      | 48       |    | 14       |  |
| Cumulative translation adjustment                                  | 523                     |      | 366      |    | (277)    |  |
| Total other comprehensive income (loss)                            | 447                     |      | 414      |    | (263)    |  |
| Total comprehensive loss   | \$<br>(66,273)          | \$   | (69,535) | \$ | (48,860) |  |

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

|   | Commo   | on Stock | Preferr | ed Stock | Additional       | Accumulated<br>Other |              | Total            |
|---|---------|----------|---------|----------|------------------|----------------------|--------------|------------------|
|   |         | Par      |         | Par      | Paid-In          | Comprehensive        | Accumulated  | Stockholders'    |
|   | Shares  | Amount   | Shares  | Amount   | Capital          | Income (Loss)        | Deficit      | Equity           |
| Balances at December 31, 2010   | 115,611 | \$ 116   |         |          | \$ 369,686       | \$ (746)             | \$ (316,945) | \$ 52,111        |
| Issuance of common stock upon<br>exercise of stock options and<br>restricted stock awards | 308     |          |         |          | 10               |                      |              | 10               |
| Issuance of common stock under  |         | -        | -       | -        |                  | -                    |              | 10               |
| Employee Stock Purchase Plan Proceeds from issuances of common stock and warrants, net of | 106     | -        | -       | -        | 132              | -                    | -            | 132              |
| issuance costs  | 38,601  | 39       | _       | _        | 91,259           | _                    | _            | 91,298           |
| Stock compensation expense  | -       | -        | _       | _        | 5,189            | -                    | _            | 5,189            |
| Total other comprehensive income  |         |          |         |          | ,                | (2.00)               |              |                  |
| (loss)  | -       | -        | -       | -        | -                | (263)                | (40 507)     | (263)            |
| Net loss  | 154.626 | 155      |         |          | 400 270          | (1,000)              | (48,597)     | (48,597)         |
| Balances at December 31, 2011 Issuance of common stock upon exercise of stock options and | 154,626 | 155      | -       | -        | 466,276          | (1,009)              | (365,542)    | 99,880           |
| restricted stock awards   | 1,222   | 1        | -       | -        | 1,954            | -                    | -            | 1,955            |
| Issuance of common stock under<br>Employee Stock Purchase Plan                            | 141     | _        | _       | _        | 307              | _                    | _            | 307              |
| Proceeds from issuances of common stock and warrants, net of                              |         |          |         |          |                  |                      |              |                  |
| issuance costs Stock compensation expense   | 26,803  | 27       | -       | -        | 71,753<br>10,439 | -                    | -            | 71,780<br>10,439 |
| Total other comprehensive income  |         |          |         |          | 10,433           | <del>-</del>         |              | 10,433           |
| (loss)  | _       | _        | _       | _        | _                | 414                  | _            | 414              |
| Net loss  | -       | -        | -       | -        | -                | -                    | (69,949)     | (69,949)         |
| Balances at December 31, 2012   | 182,792 | 183      | _       |          | 550,729          | (595)                | (435,491)    | 114,826          |
| Issuance of common stock upon   |         |          |         |          |                  | ,                    | ( / /        |                  |
| exercise of stock options and restricted stock awards                                     | 106     | _        | -       | _        | 112              | _                    | _            | 112              |
| Issuance of common stock under  | 129     |          |         |          | 224              |                      |              | 224              |
| Employee stock purchase plan<br>Restricted stock award delivered                          | 115     | -        | -       | -        | 224              | <del>-</del>         | -            | -                |
| Issuance of common stock, net of  |         |          |         |          |                  |                      |              |                  |
| issuance costs Issuance of Series B convertible   | 79,570  | 80       | -       |          | 80,919           | -                    | -            | 80,999           |
| preferred stock, net of issuance  |         |          | 40      |          | 44,000           |                      |              | 44.000           |
| costs Beneficial conversion feature of  | -       | -        | 43      | -        | 44,209           | -                    | -            | 44,209           |
| Series B convertible preferred stock  |         |          |         |          |                  |                      |              |                  |
| Deemed dividend to holders of Series  | -       | -        | -       | -        | -                | -                    | -            | -                |
| B convertible preferred stock   | -       | -        | -       | -        | -                | -                    | -            | -                |
| Initial expenses related to ATM agreement   |         |          |         |          | (143)            |                      |              | (143)            |
| Warrants exercised  | 84      | -        | -       | -        | (143)            | -                    |              | (143)            |
| Stock compensation expense  | -       | _        | _       | _        | 12,340           | <u>-</u>             | _            | 12,340           |
| Total other comprehensive income (loss)   | _       | _        | _       | -        | -                | 447                  | _            | 447              |
| Net loss  |         | <u>-</u> |         | <u>-</u> | <u>-</u>         | <u>-</u> _           | (66,720)     | (66,720)         |
| Balances at December 31, 2013   | 262,796 | \$ 263   | 43      | \$ -     | \$ 688,390       | \$ (148)             | \$ (502,211) | \$ 186,294       |

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

|  | Year E      | er 31,      |             |  |
|--|-------------|-------------|-------------|--|
|  | 2013        | 2012        | 2011        |  |
| Operating activities   |             |             |             |  |
| Net loss   | \$ (66,720) | \$ (69,949) | \$ (48,597) |  |
| Adjustments to reconcile net loss to net cash used in operating activities:                                    |             |             |             |  |
| Depreciation and amortization  | 1,327       | 1,207       | 1,303       |  |
| Amortization of intangible assets  | -           | -           | 299         |  |
| Loss (gain) on disposal of property and equipment  | 18          | 8           | 20          |  |
| Accretion of discounts and amortization of premiums of marketable securities                                   | 923         | 1,298       | 1,172       |  |
| Interest associated with long-term note payable to Symphony Dynamo Holdings LLC ("Holdings)                    | -           | 2,190       | 1,871       |  |
| Fair value adjustment of the warrant and contingent liabilities to Holdings, including the impact of the anti- |             |             |             |  |
| dilution provision associated with the common stock and warrants issued to Symphony Capital Partners, L.P.     |             |             |             |  |
| and Symphony Strategic Partners, LLC (collectively, "Symphony")  | -           | -           | (843)       |  |
| Unoccupied facility expense  | 926         | -           | -           |  |
| Stock compensation expense   | 12,340      | 10,439      | 5,189       |  |
| Changes in operating assets and liabilities:   |             |             |             |  |
| Accounts receivable  | (622)       | 8,522       | (8,526)     |  |
| Prepaid expenses and other current assets  | 677         | (922)       | 230         |  |
| Restricted cash and other assets   | 176         | (116)       | (290)       |  |
| Accounts payable   | (657)       | 126         | (289)       |  |
| Accrued liabilities and other long term liabilities  | (2,291)     | 1,916       | (2,167)     |  |
| Deferred revenues  | (4,770)     | 1,472       | 3,512       |  |
| Net cash used in operating activities  | (58,673)    | (43,809)    | (47,116)    |  |
| Investing activities   |             |             |             |  |
| Purchases of marketable securities   | (192,044)   | (206,149)   | (111,205)   |  |
| Proceeds from maturities of marketable securities  | 142,321     | 169,387     | 77,729      |  |
| Purchases of property and equipment, net   | (1,629)     | (2,931)     | (1,142)     |  |
| Net cash used in investing activities  | (51,352)    | (39,693)    | (34,618)    |  |
| Financing activities   |             |             |             |  |
| Proceeds from issuances of common stock  | 80,856      | 71,780      | 91,298      |  |
| Proceeds from issuances of preferred stock   | 44,209      | -           | -           |  |
| Proceeds from issuances of warrants  | -           | -           | -           |  |
| Proceeds from exercise of stock options and restricted stock awards  | 112         | 1,955       | 10          |  |
| Proceeds from employee stock purchase plan   | 224         | 307         | 132         |  |
| Payment of notes payable to Holdings   |             | (15,000)    | -           |  |
| Net cash provided by financing activities  | 125,401     | 59,042      | 91,440      |  |
| Effect of exchange rate changes on cash and cash equivalents   | 147         | 118         | (218)       |  |
| Net increase (decrease) in cash and cash equivalents   | 15,523      | (24,342)    | 9,488       |  |
| Cash and cash equivalents at beginning of year   | 7,599       | 31,941      | 22,453      |  |
| Cash and cash equivalents at end of year   | \$ 23,122   | \$ 7,599    | \$ 31,941   |  |
| Supplemental disclosure of cash flow information   |             |             |             |  |
| Non-cash investing and financing activities:   |             |             |             |  |
| Disposal of fully depreciated property and equipment   | \$ 86       | \$ 169      | \$ 1,181    |  |
| Net change in unrealized (loss) gain on marketable securities  | \$ (76)     | \$ 48       | \$ 14       |  |

# DYNAVAX TECHNOLOGIES CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), a clinical-stage biopharmaceutical company, develops products to prevent and treat infectious and inflammatory diseases and cancer based on Toll-like Receptor ("TLR") biology and its ability to modulate the innate immune system. Our lead product candidate is HEPLISAV-B<sup>TM</sup> (also known as "HEPLISAV"), an investigational adult hepatitis B vaccine in Phase 3 clinical development.

In addition to HEPLISAV-B, we are conducting clinical and preclinical programs that utilize our expertise in TLR biology. Our product candidates include both TLR agonists and TLR inhibitors. Our clinical stage programs include our autoimmune program partnered with GlaxoSmithKline ("GSK"), our asthma therapeutic program partnered with AstraZeneca AB ("AstraZeneca"), and our cancer immunotherapy program. We also are advancing preclinical development programs in adjuvant technology and TLR 7, 8, and 9 inhibition. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

#### **Subsidiaries**

In April 2006, we completed the acquisition of Rhein Biotech GmbH ("Rhein" or "Dynavax Europe"), a wholly-owned subsidiary in Düsseldorf, Germany. In October 2011, we formed Dynavax International, B.V., a wholly-owned subsidiary in Amsterdam, Netherlands.

#### 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The consolidated financial statements include our accounts and those of our wholly-owned subsidiaries. All significant intercompany accounts and transactions among the entities have been eliminated from the consolidated financial statements.

#### **Liquidity and Financial Condition**

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2013, we had cash, cash equivalents and marketable securities of \$189.4 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of December 31, 2013 and anticipated revenues and funding from existing agreements.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B, human clinical trials for our product candidates and additional applications and advancement of our technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or our other development programs while we seek strategic alternatives.

#### **Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make informed estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ materially from these estimates.

#### **Foreign Currency Translation**

We consider the local currency to be the functional currency for our international subsidiary, Rhein. Accordingly, assets and liabilities denominated in foreign currencies are translated into U.S. dollars using the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the year. Currency translation adjustments arising from period to period are charged or credited to accumulated other comprehensive income (loss) in stockholders' equity. For the years ended December 31, 2013, 2012 and 2011, we reported an unrealized gain of \$0.5 million, an unrealized gain of \$0.4 million and an unrealized loss of \$0.3 million, respectively. Realized gains and losses resulting from currency transactions are included in the consolidated statements of operations. For the years ended December 31, 2013, 2012 and 2011, we reported a loss of \$0.2 million, a loss of \$0.2 million and a gain of \$0.2 million, respectively, resulting from currency transactions in our consolidated statements of operations.

#### Cash, Cash Equivalents and Marketable Securities

We consider all highly liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty, to be cash equivalents. Management determines the appropriate classification of marketable securities at the time of purchase. We invest in short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We believe these types of investments 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 loans.

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the securities, with unrealized gains and losses included in accumulated other comprehensive income (loss) 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:

- Whether the investment has been in a continuous realized loss position for over 12 months;
- the duration to maturity of our investments;
- our intention and ability to hold the investments to maturity and if it is not more likely than not that we will be required to sell the investment before recovery of the amortized cost bases;
- the credit rating, financial condition and near-term prospects of the issuer; and
- · the type of investments made.

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

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

We operate in one business segment, which is the discovery and development of biopharmaceutical products. We determine our segments based on the way we organize our business by making operating decisions and assessing performance. In fiscal years 2013, 2012 and 2011, 89%, 88% and 94% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Germany. As of December 31, 2013 and 2012, 9% and 10%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

Financial instruments that are subject to concentration of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable. 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 to limit the amount of credit exposure. We currently maintain a portfolio of cash equivalents and marketable securities in a variety of securities, including short-term money market funds, U.S. government agency securities, U.S. treasury securities and municipal securities. We have not experienced any losses on our cash equivalents and marketable securities.

Accounts receivable are recorded at invoice value. We review our exposure to accounts receivable, including the requirement 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 accounts receivable.

Our products will require approval from the U.S. Food and Drug Administration ("FDA") 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 business.

We have relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single contract manufacturer to produce our first generation TLR 9 agonist, 1018 for HEPLISAV-B. The loss of our current supplier would have a significant effect on our ability to produce HEPLISAV-B for commercialization and development of our other product candidates. To date, we have manufactured only small quantities of oligonucleotides and 1018 ourselves for development purposes.

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

#### **Long-Lived Assets**

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Repair and maintenance costs are charged to expense as incurred. Leasehold improvements in both of our facilities are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter.

We evaluate the carrying value of long-lived assets, including intangible assets, whenever events or changes in business circumstances or our planned use of long-lived assets indicate, based on undiscounted future operating cash flows, that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. When an indicator of impairment exists, long-lived assets are written down to their respective fair values. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows. No impairments of purchased intangible assets have been identified during the years presented.

#### Goodwill

Our goodwill balance relates to our April 2006 acquisition of Rhein. Goodwill was recorded as the excess purchase price over tangible and intangible assets acquired and liabilities assumed based on their estimated fair value, by applying the acquisition method of accounting. Goodwill is not amortized but is subject to an annual impairment test which consists of a comparison of the fair value of the related reporting unit against its carrying amount including goodwill. If the carrying amount exceeds the fair value, impairment is calculated and recorded as a charge in the consolidated statements of operations. We determined that we have only one operating segment and there are no components of that operating segment that are deemed to be separate reporting units such that we have one reporting unit for purposes of our goodwill impairment testing. 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.

#### **Revenue Recognition**

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. 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 collectability is reasonably assured.

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. 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.

Contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are 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.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that collection is reasonably assured and the other revenue recognition criteria have been satisfied.

Revenues from manufacturing services 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.

#### **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. 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. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

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, 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, successful enrollment of patients, completion of portions of the clinical trial or similar conditions. 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 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. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2013.

#### **Stock-Based Compensation**

Stock-based compensation expense for stock options and other stock awards is estimated at the grant date based on the award's fair value-based measurement and is recognized on a straight-line basis over the award's vesting period, assuming appropriate forfeiture rates. Our determination of the fair value-based measurement of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value-based measurement of stock options granted in the future. Changes in the fair value-based measurement of stock awards could materially impact our operating results.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value-based measurement of our stock options. The Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value-based measurement of stock options, including the option's expected term and the price volatility of the underlying stock. Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the quarter of revision, as well as in the following quarters.

#### **Income Taxes**

We account for income taxes using the asset and liability method, under which deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Additionally, we 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 at December 31, 2013 and 2012 because we believe it is more likely than not that our deferred tax assets will not be realized as of December 31, 2013, and 2012.

We have no unrecognized tax benefits as of December 31, 2013, including no accrued amounts for interest and penalties. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2014. Our policy will be to recognize interest and penalties related to income taxes, if any, as a component of general and administrative expense. We are subject to income tax examinations for U.S. federal and state income taxes from 1996 forward. We are subject to tax examination in Germany from 2010 forward.

#### **Recent Accounting Pronouncements**

#### Accounting Standards Update 2013-02

In February 2013, the FASB issued ASU 2013-02, "*Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income*." This ASU expands the presentation of changes in accumulated other comprehensive income. The new guidance requires an entity to disaggregate the total change of each component of other comprehensive income either on the face of the statement of operations or as a separate disclosure in the financial statement footnotes. ASU 2013-02 is effective for fiscal years beginning after December 15, 2012. The Company adopted this guidance on a prospective basis in the first quarter of 2013 and the adoption did not have any impact on our financial position, results of operations or cash flows as there were no amounts reclassified out of accumulated other comprehensive (loss) income during the year ended December 31, 2013.

#### 3. Fair Value Measurements

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- · Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- · Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- · Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, therefore requiring an entity to develop its own assumptions.

#### **Recurring Fair Value Measurements**

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2013 and 2012 (in thousands):

|                                   | Level 1 |         | Level 2 |         | 2 Level 3 |       |     | Total   |
|-----------------------------------|---------|---------|---------|---------|-----------|-------|-----|---------|
| December 31, 2013                 |         |         |         |         |           |       |     |         |
| Money market funds                | \$      | 20,013  | \$      | -       | \$        | -     | \$  | 20,013  |
| U.S. government agency securities |         | -       |         | 167,597 |           | -     |     | 167,597 |
| Total                             | \$      | 20,013  | \$      | 167,597 | \$        |       | \$  | 187,610 |
|                                   |         |         | =       |         |           |       | === |         |
|                                   | I       | Level 1 |         | Level 2 | Le        | vel 3 |     | Total   |
| December 31, 2012                 |         |         |         |         |           |       |     | _       |
| Money market funds                | \$      | 3,140   | \$      | -       | \$        | -     | \$  | 3,140   |
| U.S. government agency securities |         | -       |         | 119,233 |           | -     |     | 119,233 |
| U.S. treasury securities          |         | -       |         | 500     |           | -     |     | 500     |
| Municipal securities              |         | -       |         | 715     |           | -     |     | 715     |
| Total                             | \$      | 3,140   | \$      | 120,448 | \$        | -     | \$  | 123,588 |

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. Government agency securities, U.S. treasury securities and municipal securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

## 4. Cash, Cash Equivalents and Marketable Securities

The following is a summary of cash, cash equivalents and marketable securities as of December 31, 2013, and 2012 (in thousands):

|  | Amortized<br>Cost |         | Unrealized<br>Gains |    | Unrealized<br>Losses |          | <br>timated<br>ir Value |
|--|-------------------|---------|---------------------|----|----------------------|----------|-------------------------|
| December 31, 2013                                      |                   |         |                     |    |                      | ,        |                         |
| Cash and cash equivalents:                             |                   |         |                     |    |                      |          |                         |
| Cash   | \$                | 1,766   | \$                  | -  | \$                   | -        | \$<br>1,766             |
| Money market funds                                     |                   | 20,013  |                     | -  |                      | -        | 20,013                  |
| U.S. government agency securities                      |                   | 1,343   |                     | -  |                      | <u>-</u> | 1,343                   |
| Total cash and cash equivalents                        |                   | 23,122  |                     | -  | · ·                  | _        | 23,122                  |
| Marketable securities available-for-sale:              |                   |         |                     |    |                      |          |                         |
| U.S. government agency securities                      |                   | 166,285 |                     | 16 |                      | (47)     | 166,254                 |
| Total marketable securities available-for-sale         |                   | 166,285 |                     | 16 |                      | (47)     | 166,254                 |
| Total cash, cash equivalents and marketable securities | \$                | 189,407 | \$                  | 16 | \$                   | (47)     | \$<br>189,376           |
| December 31, 2012                                      |                   |         |                     |    |                      |          |                         |
| Cash and cash equivalents:                             |                   |         |                     |    |                      |          |                         |
| Cash   | \$                | 1,542   | \$                  | -  | \$                   | -        | \$<br>1,542             |
| Money market funds                                     |                   | 3,140   |                     | -  |                      | -        | 3,140                   |
| Municipal securities                                   |                   | 715     |                     | -  |                      | -        | 715                     |
| U.S. government agency securities                      |                   | 2,202   |                     | -  |                      | -        | 2,202                   |
| Total cash and cash equivalents                        |                   | 7,599   |                     | -  |                      | _        | <br>7,599               |
| Marketable securities available-for-sale:              |                   |         |                     |    |                      |          |                         |
| U.S. government agency securities                      |                   | 116,986 |                     | 46 |                      | (1)      | 117,031                 |
| U.S. treasury securities                               |                   | 500     |                     | -  |                      | -        | 500                     |
| Total marketable securities available-for-sale         |                   | 117,486 |                     | 46 |                      | (1)      | <br>117,531             |
| Total cash, cash equivalents and marketable securities | \$                | 125,085 | \$                  | 46 | \$                   | (1)      | \$<br>125,130           |

The maturities of our marketable securities available-for-sale are as follows (in thousands)

|   |    | December              | r 31, | 2013         |
|---|----|-----------------------|-------|--------------|
|   | _  |                       | Es    | timated Fair |
|   | A  | <b>Amortized Cost</b> |       | Value        |
| Mature in one year or less              | \$ | 93,691                | \$    | 93,701       |
| Mature after one year through two years |    | 72,594                |       | 72,553       |
|   | \$ | 166,285               | \$    | 166,254      |

We invest in short-term money market funds, U.S. government agency securities, U.S treasury securities and municipal securities.

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2013, 2012 and 2011. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity.

#### 5. Property and Equipment

Property and equipment as of December 31, 2013, and 2012 consist of the following (in thousands):

|  | Estimated Usefu | l  |          |        |          |
|--|-----------------|----|----------|--------|----------|
|  | Life            |    | Decem    | ber 31 | l,       |
|  | (In years)      |    | 2013     |        | 2012     |
| Manufacturing equipment                        | 5-14            | \$ | 8,968    | \$     | 7,574    |
| Lab equipment                                  | 5-13            |    | 7,227    |        | 6,755    |
| Computer equipment                             | 3               |    | 1,962    |        | 1,807    |
| Furniture and fixtures                         | 3               |    | 1,056    |        | 983      |
| Leasehold improvements                         | 5-7             |    | 6,048    |        | 5,445    |
| Assets in progress                             |                 |    | 762      |        | 1,047    |
|  |                 |    | 26,023   |        | 23,611   |
| Less accumulated depreciation and amortization |                 |    | (17,317) |        | (15,646) |
| Total  |                 | \$ | 8,706    | \$     | 7,965    |

Depreciation and amortization expense on property and equipment was \$1.3 million, \$1.2 million and \$1.3 million for the years ended December 31, 2013, 2012 and 2011, respectively.

#### 6. Intangible Assets

Intangible assets consisted primarily of manufacturing process and customer relationships related to our 2006 acquisition of Rhein. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a process we use to make 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. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The manufacturing process and customer relationships were amortized over their estimated useful lives of five years. Both the manufacturing process and customer relationships intangible assets were fully amortized as of the year ended December 31, 2011. Amortization of intangible assets was zero for the years ended December 31, 2013 and 2012, and \$0.3 million for the year ended December 31, 2011.

#### 7. Current Accrued Liabilities

Current accrued liabilities as of December 31, 2013, and 2012 consist of the following (in thousands):

|   | December 31, |    |        |  |  |
|---|--------------|----|--------|--|--|
|   | <br>2013     |    | 2012   |  |  |
| Payroll and related expenses                  | \$<br>3,639  | \$ | 4,538  |  |  |
| Legal expenses                                | 338          |    | 396    |  |  |
| Third party research and development expenses | 2,403        |    | 3,207  |  |  |
| Other accrued liabilities                     | 1,786        |    | 1,922  |  |  |
| Total   | \$<br>8,166  | \$ | 10,063 |  |  |

## 8. Symphony Dynamo, Inc.

On April 18, 2006, we, Symphony and Holdings entered into a transaction involving a series of related agreements providing for the advancement of certain of our immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the "Programs"). Pursuant to these agreements, Symphony formed SDI and invested \$50 million to fund the Programs, and we licensed to Holdings our intellectual property rights related to the Programs, which were assigned to SDI. As a result of these agreements, Symphony owned 100% of the equity of Holdings, which owned 100% of the equity of SDI.

In connection with the transaction described above, Holdings granted to us an exclusive purchase option that gave us the right, but not the obligation, to acquire the outstanding equity securities of SDI, which would result in our reacquisition of the intellectual property rights that we licensed to Holdings (the "Original Purchase Option"). In exchange for the Original Purchase Option, we granted Holdings five-year warrants to purchase up to 2,000,000 shares of our common stock at an exercise price of \$7.32 per share pursuant to a warrant purchase agreement (the "Original Warrants"), and granted certain registration rights to Holdings pursuant to a registration rights agreement. We also received an exclusive option to purchase either the hepatitis B or hepatitis C therapy program (the "Program Option") during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program which resulted in the recognition of a \$15 million liability to Symphony. We remained primarily responsible for the development of the cancer and hepatitis C therapy programs in accordance with a development plan and related development budgets that we agreed to with Holdings.

Prior to the acquisition of all of the outstanding equity of SDI on December 30, 2009, we consolidated the financial position and results of operations of SDI. In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the Original Purchase Option (the "Amended Purchase Option"). We completed the acquisition of all of the outstanding equity of SDI on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to Symphony and certain of its co-investors: (i) 13,000,000 shares of common stock (the "Shares"); (ii) 5-year warrants to purchase 2,000,000 shares of common stock with an exercise price of \$1.94 per share (the "Warrants"); and (iii) a non-interest bearing note in the principal amount of \$15 million, due December 31, 2012, payable in cash, our common stock or a combination thereof at our discretion, which obligation was previously payable solely in cash on April 18, 2011 (the "Note"). In addition, we agreed to contingent cash payments from us equal to 50% of the first \$50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies originally licensed to SDI. The Original Warrants held by Symphony were cancelled as part of this transaction.

We were obligated to make future contingent cash payments to the former Holdings shareholders related to certain payments received by us, if any, from future partnering agreements pertaining to our hepatitis C and cancer therapy programs. We estimated the valuation of this contingent liability using a discounted cash flow model. The discounted cash flow model was derived from management's assumptions regarding the timing, amounts, and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at a rate of 16% for the fiscal year ended December 31, 2010.

Changes in the fair value of the contingent consideration liability were recognized in "other income (expense)" in the consolidated statements of operations in the period of the change. During the fiscal year ended December 31, 2010, we reduced the assumed probability of our receipt of upfront and milestone payments from a potential partnership and extended the timing of when these expected receipts would occur. In addition, based on our assumptions regarding our beta and risk free interest rate used in the discounted cash flow model, the change in fair value of the contingent consideration liability resulted in other income of \$2.2 million for the fiscal year ended December 31, 2010. During the year ended December 31, 2011, we determined that we would not receive any upfront or milestone payments from a potential partnership for our hepatitis C therapy program and, therefore, estimated the fair value of the liability to be zero as of December 31, 2011 resulting in other income of \$0.8 million. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement.

We recorded the acquisition of all of the outstanding equity of SDI pursuant to the Amended Purchase Option as a return of equity to the noncontrolling interest. The acquisition was accounted for as a capital transaction that did not affect our consolidated net loss. However, because the acquisition was accounted for as a capital transaction, the consideration paid in excess of the carrying value of the noncontrolling interest in SDI is treated as a deemed dividend at the time for purposes of reporting net loss and earnings per share.

The estimated fair values of the warrants transferred were calculated using the Black-Scholes valuation model.

We estimated the fair value of the Note using a net present value model with a discount rate of 17%. Imputed interest was recorded as interest expense over the term of the loan using the interest rate method. We paid in cash the \$15 million principal balance of the Note on December 31, 2012.

The Shares and Warrants were subject to certain anti-dilution protection in the event that we issued other equity securities within six months from December 30, 2009. As a result of an equity offering completed in April 2010 prior to the expiration of the anti-dilution provision, Symphony received an additional 1,076,420 shares of common stock ("April 2010 Shares") and warrants to purchase 7,038,210 shares of common stock ("April 2010 Warrants") having the same terms as the warrants sold in the offering, which have an exercise price of \$1.50 per share and a term of five years. The Warrants issued on December 30, 2009 were cancelled upon the issuance of the April 2010 Warrants.

The fair value of the April 2010 Shares and incremental fair value of the April 2010 Warrants provided to Symphony, as measured upon issuance and remeasured at June 30, 2010, resulted in non-operating expense of \$11.1 million in the second quarter of 2010. This also resulted in an increase of \$9.5 million to the warrant liability and an increase of \$1.6 million to additional paid in capital as of June 30, 2010. Following the expiration date of Symphony's anti-dilution protection, on June 30, 2010, the value of the April 2010 Warrants of \$12.0 million was reclassified into stockholders' equity in the consolidated balance sheets. As of December 31, 2013, warrants to purchase 6,765,128 shares remained outstanding.

#### 9. Commitments and Contingencies

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are 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. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense.

During September 2013, we decided not to occupy a portion of our facility in Berkeley, California. As a result, we recorded a one-time estimated unoccupied facility expense of \$0.9 million for the year ended December 31, 2013, representing the present value of the rent payments and other costs associated with the lease, net of estimated sublease income, for the remaining life of the operating lease.

Total net rent expense related to our operating leases for the years ended December 31, 2013, 2012 and 2011, was \$1.9 million, \$1.7 million and \$1.7 million, respectively. Deferred rent was \$0.6 million as of December 31, 2013 and 2012.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2013, excluding payments from sublease payments, are as follows (in thousands):

| Years ending December 31, |              |
|---------------------------|--------------|
| 2014                      | \$<br>2,233  |
| 2015                      | 2,282        |
| 2016                      | 2,333        |
| 2017                      | 2,382        |
| 2018                      | 1,351        |
| Thereafter                | 2,499        |
| Total                     | \$<br>13,080 |

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, 2013, and is collateralized by a certificate of deposit for \$0.4 million, which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20 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 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of approximately 0.2 million Euros. The letter of credit remained outstanding through December 31, 2013 and is collateralized by a certificate of deposit for 0.2 million Euros, which has been included in restricted cash in the consolidated balance sheets as of December 31, 2013 and 2012.

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 addition, 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 up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and material manufacturers of our product candidates. As of December 31, 2013, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$4.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

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, if any, of certain products originating from the licensed technologies.

## 0. Collaborative Research, Development and License Agreements

#### GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize TLR inhibitors. Under the terms of the arrangement, we agreed to conduct research and early clinical development in up to four programs: the Lead TLR 7/9 program, a Follow-On TLR 7/9 program, and up to two other TLR programs. In 2011 we began development of a TLR 8 program as one of the two additional programs under the collaboration. GSK subsequently returned all rights to this program to us.

We are currently conducting a Phase 1 clinical trial in the Lead TLR 7/9 program with DV1179 in systemic lupus erythematosus patients. The Company is not currently performing any activities on the Follow-On TLR 7/9 program. GSK has not yet chosen to initiate development of the remaining program under the agreement. In December 2013, we amended our agreement with GSK to extend the research term until conclusion of the ongoing phase 1 study of DV1179. In addition, the exclusivity provisions of the agreement were modified, giving us rights to immediately begin preclinical and clinical research on inhibitors of TLR 7 and 9 (other than DV1179) for oncology indications.

GSK can exercise its exclusive option to license each program. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. If GSK exercises their option on the Lead TLR 7/9 program, then we are eligible to receive payments of up to approximately \$125 million, comprised of contingent option exercise payments and additional payments based on GSK's achievement of certain development, regulatory and commercial objectives.

We are also eligible to receive up to \$60 million if aggregate worldwide annual net sales milestones are achieved and tiered royalties ranging from the mid–single digit to mid-teens on sales of any products originating from the collaboration. We have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of \$10 million in 2008. The deliverables under this arrangement did not have stand-alone value and so did not qualify as separate units of accounting. In 2011, we earned and recognized \$12 million in substantive development milestone payments related to the initiation of Phase I and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients. In 2011, we earned and recognized \$3 million in substantive development milestone payments related to the initiation of development of the TLR 8 program.

Revenue from the initial payment from GSK was deferred and is being recognized over the expected period of performance under the agreement, initially estimated to be seven years. In the fourth quarter of 2013 we reevaluated and revised the expected period of performance under the agreement from seven years to six years resulting in the recognition of \$0.3 million of additional revenue in 2013.

The following table summarizes the revenues recognized under our agreement with GSK (in thousands):

|                   |           | Year ended December 31, |          |       |    |           |  |  |      |  |
|-------------------|-----------|-------------------------|----------|-------|----|-----------|--|--|------|--|
|                   | 2013 2012 |                         | 2013 201 |       |    | 2013 2012 |  |  | 2011 |  |
| Initial payment   | \$        | 1,702                   | \$       | 1,428 | \$ | 1,428     |  |  |      |  |
| Milestone revenue |           | -                       |          | -     |    | 15,000    |  |  |      |  |
| Total             | \$        | 1,702                   | \$       | 1,428 | \$ | 16,428    |  |  |      |  |

As of December 31, 2013 and 2012, deferred revenue relating to the initial payment was \$2.5 million and \$4.2 million, respectively.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause upon prior written notice within a specified window of time dependent upon the stage of clinical development of the programs.

#### AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR 9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease.

In October 2011, we amended our agreement with AstraZeneca to provide that we will conduct initial clinical development of AZD1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a, estimated to total approximately \$20 million. We received an initial payment of \$3 million to begin the clinical development program. In the first quarter of 2012, we received a \$2.6 million payment to advance AZD1419 into preclinical toxicology studies and these toxicology studies were completed in the third quarter of 2012. We and AstraZeneca have agreed to advance AZD1419 towards a Phase 1 clinical trial, which resulted in a development funding payment of \$6 million, received in the fourth quarter of 2012. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a \$20 million milestone payment and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. We are eligible to receive additional milestone payments, which we have determined to be substantive milestones, of up to approximately \$100 million, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Revenue from the initial payment was deferred and is being recognized over the expected period of performance under the agreement, which is approximately 50 months. Revenue from the development funding payment is being recognized as the development work is performed.

The following table summarizes the revenues earned under our agreement with AstraZeneca (in thousands):

|                                    | Year ended December 31, |    |       |    |      |  |  |
|------------------------------------|-------------------------|----|-------|----|------|--|--|
|                                    | <br>2013 2012           |    |       |    | 2011 |  |  |
| Initial payments                   | \$<br>720               | \$ | 720   | \$ | 120  |  |  |
| Performance of research activities | 2,507                   |    | 2,462 |    | 642  |  |  |
| Total                              | \$<br>3,227             | \$ | 3,182 | \$ | 762  |  |  |

As of December 31, 2013 and 2012, total deferred revenue from the initial payment and development funding payments was \$4.8 million and \$7.7 million, respectively.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

## National Institutes of Health ("NIH") and Other Funding

We have been awarded various grants from the NIH and the NIH's National Institute of Allergy and Infectious Disease ("NIAID") in order to fund research. The awards are related to specific research objectives and we earn revenue as the related research expenses are incurred. We have earned revenue during the periods ended December 31, 2013 and 2012 from the following awards:

- · September 2013, NIH awarded us \$0.2 million to fund research in developing TLR antagonists for therapy of hepatic fibrosis and cirrhosis.
- · June 2012, NIH awarded us \$0.6 million to fund research in screening for inhibitors of TLR 8 for treatment of autoimmune diseases.
- · May 2012, NIH awarded us \$0.4 million to fund development of TLR 8 inhibitors for treatment of rheumatoid arthritis.
- · July 2011, NIH awarded us \$0.6 million to fund research in preclinical models of skin autoimmune inflammation.
- · August 2010, NIAID awarded us a grant to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study will be one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. We have been awarded a total of \$1.4 million under this grant.
- · July 2010, NIH awarded us \$0.6 million to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus.
- · September 2008, NIAID awarded us a five-year \$17 million contract to develop our oligonucleotide technology using TLR 9 agonists as vaccine adjuvants. The contract supports adjuvant development for anthrax as well as other disease models.

The following table summarizes the revenues recognized under the various arrangements with the NIH and NIAID (in thousands):

|                         | Year ended December 31, |    |       |    |       |  |  |  |
|-------------------------|-------------------------|----|-------|----|-------|--|--|--|
|                         | <br>2013                |    | 2012  |    | 2011  |  |  |  |
| NIAID contracts         | \$<br>4,103             | \$ | 3,571 | \$ | 2,730 |  |  |  |
| All other NIH contracts | 1,035                   |    | 368   |    | 380   |  |  |  |
| Total grant revenue     | \$<br>5,138             | \$ | 3,939 | \$ | 3,110 |  |  |  |

#### 11. Net Loss Per Share

Basic net loss per share allocable to common stockholders is calculated by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share allocable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period and giving effect to all potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, outstanding stock options, stock awards, warrants and Series B Convertible Preferred Stock are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share allocable to common stockholders when their effect is dilutive.

|  | December 31, |             |             |  |  |  |  |
|--|--------------|-------------|-------------|--|--|--|--|
|  | 2013         | 2012        | 2011        |  |  |  |  |
| Basic and diluted net loss per share (in thousands, except per share amounts):         |              |             |             |  |  |  |  |
| Numerator:   |              |             |             |  |  |  |  |
| Net loss   | (66,720)     | (69,949)    | (48,597)    |  |  |  |  |
| Preferred stock deemed dividend  | (8,469)      | -           | -           |  |  |  |  |
| Net loss allocable to common stockholders  | \$ (75,189)  | \$ (69,949) | \$ (48,597) |  |  |  |  |
| Denominator for basic and diluted net loss per share allocable to common stockholders: |              |             |             |  |  |  |  |
| Weighted-average common shares outstanding   | 196,275      | 170,469     | 125,101     |  |  |  |  |
| Basic and diluted net loss per share allocable to common stockholders                  | \$ (0.38)    | \$ (0.41)   | \$ (0.39)   |  |  |  |  |

Outstanding warrants, stock options, Series B Convertible Preferred Stock and stock subject to repurchase by us under stock awards were excluded from the calculation of net loss per share allocable to common stockholders as the effect of their inclusion would have been anti-dilutive.

|   | December 31, |        |        |  |  |
|---|--------------|--------|--------|--|--|
|   | 2013         | 2012   | 2011   |  |  |
| Outstanding securities not included in diluted net loss per share calculation (in thousands): |              |        |        |  |  |
| Stock options and stock awards  | 17,040       | 15,561 | 11,101 |  |  |
| Series B Convertible Preferred Stock (as converted to common stock)                           | 43,430       | -      | -      |  |  |
| Warrants  | 12,464       | 12,714 | 25,729 |  |  |
|   | 72,934       | 28,275 | 36,830 |  |  |

#### 12. Preferred Stock, Common Stock and Warrants

#### **Authorized Shares**

On May 29, 2013 the stockholders approved an increase in the number of authorized shares of common stock from 250,000,000 to 350,000,000. The increase in authorized shares was effected pursuant to a Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (the "Certificate of Amendment"), filed with the Secretary of State of the State of Delaware on May 30, 2013.

#### **Preferred Stock Outstanding**

As of December 31, 2013 there were 5,000,000 shares of preferred stock authorized and 43,430 shares outstanding.

In October 2013 the Company sold 43,430 shares of \$0.001 par value Series B Convertible Preferred Stock for a purchase price of \$1,075 per share and gross proceeds of approximately \$46.7 million in an underwritten public offering. After issuance costs of approximately \$2.5 million, the net proceeds from the offering were approximately \$44.2 million.

Each share of Series B Convertible Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting the Series B Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder and its affiliates would own more than 9.98% of the total number of shares of common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock will receive a payment equal to \$0.001 per share before any proceeds are distributed to the common stockholders. Shares of Series B Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Convertible Preferred Stock is required to amend the terms of the Series B Convertible Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Company's board of directors. The Series B Convertible Preferred Stock ranks senior to the Company's common stock as to distributions of assets upon the Company's liquidation, dissolution or winding up, whether voluntarily or involuntarily. The Series B Convertible Preferred Stock may rank senior to, on parity with or junior to any class or series of the Company's capital stock created in the future depending upon the specific terms of such future stock issuance.

The fair value of the common stock into which the Series B Convertible Preferred Stock is convertible exceeded the allocated purchase price of the Series B Convertible Preferred Stock by \$8.5 million on the date of issuance, for which the Company recorded a deemed dividend. The Company recognized the deemed dividend equal to the number of shares of Series B Convertible Preferred Stock sold on October 30, 2013 multiplied by the difference between the value of the common stock and the Series B Convertible Preferred Stock conversion price per share on that date. The dividend was reflected as a one-time, non-cash, deemed dividend to the holders of Series B Convertible Preferred Stock on the date of issuance, which is the date the stock first became convertible.

#### **Preferred Stock Rights**

On November 4, 2008, our Board of Directors declared a dividend of one preferred share purchase right (a "Right") for each outstanding share of our Common Stock, par value \$0.001 per share (the "Common Shares"). The dividend was payable on November 17, 2008 to the stockholders of record on that date. Each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the "Preferred Shares"), at a price of \$6.00 per one one-hundredth of a Preferred Share, subject to adjustment. Upon the acquisition of, or announcement of the intent to acquire, 20 percent or more of our outstanding Common Shares by a person, entity or group of affiliated or associated persons ("Acquiring Person"), each holder of a Right, other than Rights held by the Acquiring Person, will have the right to purchase that number of Common Shares having a market value of two times the exercise price of the Right. If we are acquired in a merger or other business combination transaction or 50 percent or more of our assets or earning power are sold to an Acquiring Person, each holder of a Right will thereafter have the right to purchase, at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right. The Rights plan is intended to maximize the value of the Company in the event of an unsolicited attempt to take over the Company in a manner or on terms not approved by the Company's Board of Directors. The Rights will expire on November 17, 2018, unless the Rights are earlier redeemed or exchanged by the Company.

#### **Common Stock Outstanding**

In October 2013 we completed an underwritten public offering of 79,570,000 shares of our common stock to the public at \$1.075 per share. The gross proceeds to us from this offering were approximately \$85.5 million. After deducting issuance costs of approximately \$4.5 million, the net proceeds from the offering were approximately \$80.9 million.

On March 29, 2013, we entered into an At Market Issuance Sales Agreement (the "Agreement") with MLV & Co. LLC ("MLV") under which we may offer and sell our common stock having aggregate sales proceeds of up to \$50,000,000 from time to time through MLV as our sales agent. Sales of our common stock through MLV, if any, will be made by means of ordinary brokers' transactions on the NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and MLV. MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV a commission of up to 3.0% of the gross sales proceeds of any common stock sold through MLV under the Agreement. No sales of our common stock have taken place under this Agreement as of December 31, 2013.

On May 9, 2012, we completed an underwritten public offering of 17,500,000 shares of our common stock to the public at \$4.25 per share. The net proceeds to us from this offering were \$69.6 million, after deducting offering expenses.

On November 3, 2011, we completed an underwritten public offering of 27,600,000 shares of our common stock including 3,600,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of \$2.50 per share. The net proceeds to us from this offering were \$64.5 million, after deducting offering expenses.

On November 2, 2010, we completed an underwritten public offering of 26,450,000 shares of our common stock including 3,450,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters at a price to the public of \$1.70 per share. The net proceeds to us from this offering were \$42.0 million, after deducting offering expenses.

On September 20, 2010, we entered into a Purchase Agreement with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of \$30.0 million of shares of our common stock (the "Purchase Shares") over the 25-month term of the Purchase Agreement. Under the Purchase Agreement, we agreed to pay Aspire Capital a commitment fee equal to 4% of \$30 million in consideration for Aspire Capital's obligation to purchase up to \$30 million of our common stock. We paid this commitment fee of \$1.2 million by the issuance of 600,000 shares of our common stock and this fee was recorded as a cost of raising capital and netted against the gross proceeds from the Purchase Agreement in September 2010. During 2010, we sold 2,350,000 shares of common stock to Aspire Capital for \$3.3 million and during 2011 we sold 10,995,210 shares of common stock for \$26.7 million, which totaled the proceeds available to us of \$30 million under the Purchase Agreement.

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of \$41.1 million, after deducting offering expenses of approximately \$3.0 million, from the sale of 30,293,000 units at a per unit price of \$1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of \$1.50 per share, and is exercisable for a period of five years from the date of issuance. From this offering, warrants to purchase an aggregate of 10,913,873 shares of our common stock were outstanding as of December 31, 2013 (including the warrants to purchase 6,765,128 shares provided to Symphony as described in Note 8 "Symphony Dynamo, Inc.").

#### Warrants

In connection with a 2007 loan agreement that was subsequently terminated in 2008, we issued warrants to purchase up to 3,550,000 shares of our common stock as follows:

| Warrant Issuance Date | Shares Issuable (in thousands) | Expiration<br>Date | Exercise Price per Share | December 31, 2013<br>(in thousands) |
|-----------------------|--------------------------------|--------------------|--------------------------|-------------------------------------|
| July 18, 2007         | 1,250                          | 2/26/2014          | 5.13                     | 1,250                               |
| October 18, 2007      | 1,300                          | 2/26/2014          | 1.68                     | -                                   |
| December 27, 2007     | 300                            | 2/26/2014          | 5.65                     | 300                                 |
| December 27, 2007     | 700                            | 2/26/2014          | 1.68                     | -                                   |
| Total                 | 3,550                          |                    |                          | 1,550                               |

As of December 31, 2013, warrants to purchase an aggregate of approximately 12,500,000 shares of our common stock were outstanding. The warrants are exercisable at a weighted average price of \$1.96 per share. During the years ended December 31, 2013, and 2012, warrants were exercised to purchase an aggregate of approximately 250,000 and 13,000,000 shares, respectively, of our common stock.

#### 13. Equity Plans and Stock-Based Compensation

#### **Stock Plans**

As of December 31, 2013, we had three share-based compensation plans.

2004 Stock Incentive Plan ("2004 Plan")

The 2004 Plan was adopted in January 2004 by the Board of Directors and stockholders and became effective on February 11, 2004. This plan provided for the issuance of up to 3,500,000 shares of our common stock plus an annual increase. Subsequently, we discontinued granting stock options under the 1997 Plan. Options under the 2004 Plan were granted for periods of up to ten years and the exercise price of all stock options granted under the 2004 Plan was at least equal to 100% of the fair market value of the common stock on the date of grant. If, however, incentive stock options were 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. The 2004 Plan authorizes the issuance of various forms of stock-based awards including stock options, restricted stock, restricted stock units and other equity awards to employees, consultants and members of the board of directors. As of December 31, 2013, options to purchase 4,066,277 shares of common stock remained outstanding under the 2004 Plan.

2010 Employment Inducement Award Plan ("Inducement Plan")

The Inducement Plan was adopted in January 2010 by our Board of Directors to induce qualified individuals to join Dynavax. This Inducement Plan provided for the issuance of up to 1,500,000 shares of our common stock and became effective on January 8, 2010. Stockholder approval of the Inducement Plan is not required under NASDAQ Marketplace Rule 5635(c)(4). As of December 31, 2013, options to purchase 743,625 shares of common stock remained outstanding under the Inducement Plan.

#### 2011 Equity Incentive Plan ("2011 Plan")

The 2011 Plan was approved by the Company's stockholders and adopted in January 2011. On May 29, 2013, the stockholders of the Company approved an amendment to the 2011 Plan to increase the number of shares of common stock authorized for issuance under the plan by 10,000,000. The 2011 Plan, as amended, provides for the issuance of up to 25,000,000 shares of our common stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 Plan is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the 2011 Plan have a term of 10 years unless earlier terminated by the Board of Directors. After the adoption of the 2011 Plan, no additional awards were granted under either the 2004 Plan or the Inducement Plan. As of January 6, 2011, all shares subject to awards outstanding under the 2004 Plan and Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans. As of December 31, 2013, options to purchase 10,954,940 shares of common stock remained outstanding under the 2011 Plan. As of December 31, 2013, there were 13,666,964 shares of common stock reserved for issuance under the 2011 Plan.

Activity under our stock plans is set forth below:

|  |                               |                  | Weighted-<br>Average |                        |
|--|-------------------------------|------------------|----------------------|------------------------|
|  | Shares                        | Weighted-Average | Remaining            | Aggregate              |
|  | <b>Underlying Outstanding</b> | Exercise         | Contractual          | <b>Intrinsic Value</b> |
|  | <b>Options (in thousands)</b> | Price Per Share  | Term (years)         | (in thousands)         |
| Balance at December 31, 2012                     | 13,806                        | \$ 3.38          |                      |                        |
| Options granted                                  | 5,614                         | 2.69             |                      |                        |
| Options exercised                                | (131)                         | 1.43             |                      |                        |
| Options cancelled:                               |                               |                  |                      |                        |
| Options forfeited (unvested)                     | (2,555)                       | 3.31             |                      |                        |
| Options cancelled (vested)                       | (969)                         | 3.34             |                      |                        |
| Balance at December 31, 2013                     | 15,765                        | 3.17             | 5.26                 | \$ 1,427               |
| Vested and expected to vest at December 31, 2013 | 15,765                        | 3.17             | 5.26                 | \$ 1,427               |
| Exercisable at December 31, 2013                 | 10,628                        | 3.36             | 3.61                 | \$ 1,289               |
|  |                               |                  |                      |                        |

The total intrinsic value of stock options exercised during the years ended December 31, 2013, 2012 and 2011 was, \$0.3 million, \$2.7 million and \$0.1 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2013, 2012 and 2011 was, \$12.1 million, \$9.6 million and \$2.8 million, respectively.

Our non-vested stock awards are comprised of restricted stock units granted with performance-based vesting criteria. A summary of the status of non-vested restricted stock units as of December 31, 2013, and activities during 2013 is summarized as follows:

| Number of Shares       Average Grant-Date Fair Date Fair (In thousands)       Value         Non-vested as of December 31, 2012       1,755       \$ 4,23         Granted       250       \$ 1,23         Vested       (115)       \$ 1,10         Forfeited or expired       (615)       \$ 4,23         Non-vested as of December 31, 2013       1,275       \$ 3,93 |                                    |                | Weighted-     |
|---|------------------------------------|----------------|---------------|
| Shares<br>(In thousands)Date Fair<br>(Value)Non-vested as of December 31, 20121,7554,23Granted2501,23Vested(115)1,10Forfeited or expired(615)4,23   |                                    |                | Average       |
| Kon-vested as of December 31, 2012         (In thousands)         Value           Non-vested as of December 31, 2012         1,755         \$ 4.23           Granted         250         \$ 1.23           Vested         (115)         \$ 1.10           Forfeited or expired         (615)         \$ 4.23  |                                    | Number of      | <b>Grant-</b> |
| Non-vested as of December 31, 2012       1,755       4.23         Granted       250       \$ 1.23         Vested       (115)       \$ 1.10         Forfeited or expired       (615)       \$ 4.23   |                                    | Shares         | Date Fair     |
| Granted       250       \$ 1.23         Vested       (115)       \$ 1.10         Forfeited or expired       (615)       \$ 4.23   |                                    | (In thousands) | Value         |
| Vested       (115) \$ 1.10         Forfeited or expired       (615) \$ 4.23   | Non-vested as of December 31, 2012 | 1,755          | \$ 4.23       |
| Forfeited or expired (615) \$ 4.23  | Granted                            | 250            | \$ 1.23       |
| <u> </u>  | Vested                             | (115)          | \$ 1.10       |
| Non-vested as of December 31, 2013 1,275 \$ 3.93  | Forfeited or expired               | (615)          | \$ 4.23       |
|   | Non-vested as of December 31, 2013 | 1,275          | \$ 3.93       |

Stock-based compensation expense related to restricted stock units was approximately \$0.1 million for the year ended December 31, 2013. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2013, based on our stock price on that date, was \$2.5 million.

The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2013 and 2012 was, \$1.23 and \$4.23, respectively. No restricted stock units were granted during 2011. The total fair value of restricted stock units vested during the years ended December 31, 2013, 2012, and 2011 was, \$0.1 million, \$0.2 million, and \$0.8 million, respectively.

#### **Stock-Based Compensation**

Under our stock-based compensation plans, option awards generally vest over a four-year period contingent upon continuous service and expire ten years from the date of grant (or earlier upon termination of continuous service). The Company has also granted performance-based equity awards to certain of our employees under the 2011 Plan, the 2004 Plan and the Inducement Plan. As of December 31, 2013, 1,922,466 shares were outstanding related to options and restricted stock units subject to these performance-based vesting criteria. 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:

|                             |    | Stock Options Year Ended December 31, |    |      |    |      | <b>Employee Stock Purchase Plan</b> |      |                |      |    |      |  |  |  |  |
|-----------------------------|----|---------------------------------------|----|------|----|------|-------------------------------------|------|----------------|------|----|------|--|--|--|--|
|                             |    |                                       |    |      |    |      |                                     | Year | i <del>,</del> |      |    |      |  |  |  |  |
|                             | 2  | 2013                                  |    | 2012 |    | 2011 |                                     | 2013 |                | 2012 |    | 2011 |  |  |  |  |
| Weighted-average fair value | \$ | 2.41                                  | \$ | 3.30 | \$ | 2.76 | \$                                  | 0.93 | \$             | 3.54 | \$ | 2.09 |  |  |  |  |
| Risk-free interest rate     |    | 1.1%                                  | ,  | 0.5% |    | 1.3% | ,                                   | 0.2% | )              | 0.2% |    | 0.3% |  |  |  |  |
| Expected life (in years)    |    | 5.9                                   |    | 4.2  |    | 4.0  |                                     | 1.3  |                | 1.1  |    | 1.2  |  |  |  |  |
| Volatility                  |    | 1.4                                   |    | 1.6  |    | 1.6  |                                     | 0.8  |                | 1.6  |    | 1.6  |  |  |  |  |

Expected volatility is based on historical volatility of our stock price. The expected life of options granted is estimated based on historical option exercise and employee termination data, while giving consideration to options that have not yet completed a full life cycle. Our senior management, who hold a majority of the options outstanding, and other employees 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. The dividend yield is zero percent for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable.

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

|  | Year Ended December 31, |        |    |        |    |       |  |
|--|-------------------------|--------|----|--------|----|-------|--|
|  | - 2                     | 2013   |    | 2012   |    | 2011  |  |
| Employees and directors stock-based compensation expense | \$                      | 11,828 | \$ | 10,439 | \$ | 5,185 |  |
| Non-employees stock-based compensation expense           |                         | 512    |    | -      |    | 4     |  |
| Total  | \$                      | 12,340 | \$ | 10,439 | \$ | 5,189 |  |
|  |                         |        |    |        | _  |       |  |

Very Ended December 21

|         | Year Ended December 31, |                                  |                                     |   |  |  |
|---------|-------------------------|----------------------------------|-------------------------------------|---|--|--|
| <u></u> | 2013                    |                                  | 2012                                |   | 2011   |  |
| \$      | 4,228                   | \$                               | 3,514                               | \$  | 2,103  |  |
|         | 8,112                   |                                  | 6,925                               |   | 3,086  |  |
| \$      | 12,340                  | \$                               | 10,439                              | \$  | 5,189  |  |
|         | \$                      | <b>2013</b><br>\$ 4,228<br>8,112 | <b>2013</b><br>\$ 4,228 \$<br>8,112 | 2013     2012       \$ 4,228     \$ 3,514       8,112     6,925 | 2013     2012       \$ 4,228     \$ 3,514     \$ 8,112       6,925 |  |

Stock based compensation expense recognized in 2013 and 2012 includes \$4.9 million related to employee severance arrangements and \$0.5 million for awards to non-employees for the year ended December 31, 2013 and \$1.5 million related to employee severance arrangements for the same period in 2012. During the year ended December 31, 2013, we recognized \$1.3 million in additional stock-based compensation expense due to the modification of the terms of stock options for five employees. During the year ended December 31, 2012, we recognized \$0.7 million in additional stock-based compensation expense due to the modification of the terms of stock options for one employee.

As of December 31, 2013, the total unrecognized compensation cost related to non-vested stock options deemed probable of vesting, including all stock options with time-based vesting, net of estimated forfeitures, amounted to \$10.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.8 years. As of December 31, 2013, the total unrecognized compensation cost related to non-vested stock options not deemed probable of vesting, net of estimated forfeitures, amounted to \$3.8 million.

As of December 31, 2013, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan, amounted to \$0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years.

## **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, 2013, 996,000 shares were 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 have acquired 828,414 shares of our common stock under the Purchase Plan. As of December 31, 2013, 167,586 shares of our common stock remained available for future purchases.

## 14. Employee Benefit Plan

We maintain a 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

Consolidated income (loss) before provision for income taxes consisted of the following (in thousands):

|          | Year Ended December 31, |    |          |    | .,       |
|----------|-------------------------|----|----------|----|----------|
|          | <br>2013                |    | 2012     |    | 2011     |
| U.S.     | \$<br>(67,004)          | \$ | (70,792) | \$ | (49,990) |
| Non U.S. | 284                     |    | 843      |    | 1,393    |
| Total    | \$<br>(66,720)          | \$ | (69,949) | \$ | (48,597) |

No income tax expense was recorded for the years ended December 31, 2013, 2012 and 2011 due to net operating loss carryforwards to offset the net income at Dynavax Europe and a valuation allowance which offsets the deferred tax assets. The difference between the consolidated income tax benefit and the amount computed by applying the federal statutory income tax rate to the consolidated loss before income taxes was as follows (in thousands):

|  | Year Ended December 31, |          |    | ,        |    |          |
|--|-------------------------|----------|----|----------|----|----------|
|  |                         | 2013     |    | 2012     |    | 2011     |
| Income tax benefit at federal statutory rate | \$                      | (22,678) | \$ | (23,650) | \$ | (16,523) |
| State tax                                    |                         | (178)    |    | (89)     |    | (2,586)  |
| Business credits                             |                         | (2,515)  |    | -        |    | (1,394)  |
| Deferred compensation charges                |                         | 3,072    |    | 1,002    |    | 595      |
| Change in valuation allowance                |                         | 22,354   |    | 21,966   |    | 18,099   |
| Change in foreign tax rates                  |                         | -        |    | -        |    | (34)     |
| Change in the fair value measurements        |                         | -        |    | -        |    | 286      |
| Non-deductible debt discount                 |                         | -        |    | -        |    | 509      |
| Deemed dividend                              |                         | -        |    | -        |    | 273      |
| Prior year true up                           |                         | -        |    | -        |    | -        |
| Other  |                         | (55)     |    | 771      |    | 775      |
| Total income tax expense                     | \$                      | -        | \$ | -        | \$ | -        |

Deferred tax assets and liabilities as of December 31, 2013 and 2012 consisted of the following (in thousands):

|                                    | December 31,  |    |           |
|------------------------------------|---------------|----|-----------|
|                                    | <br>2013      |    | 2012      |
| Deferred tax assets:               |               |    |           |
| Net operating loss carry forwards  | \$<br>147,655 | \$ | 127,529   |
| Research tax credit carry forwards | 21,336        |    | 18,163    |
| Accruals and reserves              | 9,501         |    | 8,529     |
| Capitalized research costs         | 10,662        |    | 12,757    |
| Deferred revenue                   | 2,486         |    | 2,180     |
| Other                              | 1,222         |    | 1,221     |
|                                    | <br>192,862   |    | 170,379   |
| Less valuation allowance           | (192,733)     |    | (170,232) |
| Total deferred tax assets          | <br>129       |    | 147       |
| Deferred tax liabilities:          |               |    |           |
| Fixed Assets                       | (162)         |    | (86)      |
| Other                              | 33            |    | (61)      |
| Total deferred tax liabilities     | (129)         |    | (147)     |
| Net deferred tax assets            | \$<br>-       | \$ | -         |

The tax benefit of net operating losses, temporary differences and credit carryforwards is required to be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance. The valuation allowance increased by \$22.5 million, \$22.0 million and \$18.1 million during the years ended December 31, 2013, 2012 and 2011, respectively. The amount of the valuation allowance for deferred tax assets associated with excess tax deductions from stock based compensation arrangements that will be allocated to contributed capital if the future tax benefits are subsequently recognized is \$0.3 million.

We have not recorded deferred income taxes applicable to undistributed earnings of a foreign subsidiary that are indefinitely reinvested in foreign operations. Generally, such earnings become subject to U.S. tax upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of the deferred tax liability on such undistributed earnings.

As of December 31, 2013, we had federal net operating loss carryforwards of approximately \$384.1 million, which will expire in the years 2018 through 2033 and federal research and development tax credits of approximately \$13.8 million, which expire in the years 2018 through 2033.

As of December 31, 2013, we had potential net operating loss carryforwards for California state income tax purposes of approximately \$219.7 million, which expire in the years 2014 through 2033, and California state research and development tax credits of approximately \$11.5 million which do not expire.

As of December 31, 2013, we had net operating loss carryforwards for foreign income tax purposes of approximately \$27.8 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. Due to past equity issuances and changes in ownership of Dynavax common stock, we believe that our ability to use some of our net operating losses and tax credits in the future may be limited.

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

|   | Year Ended December 31, 2013 |                 |    |                 |    |                   |    |                   |
|---|------------------------------|-----------------|----|-----------------|----|-------------------|----|-------------------|
|   |                              | Q1              |    | Q2              |    | Q3                |    | Q4                |
| Revenues  | \$                           | 2,085           | \$ | 3,392           | \$ | 2,927             | \$ | 2,847             |
| Net loss  | \$                           | (20,825)        | \$ | (17,164)        | \$ | (15,675)          | \$ | (13,056)          |
| Net loss allocable to common stockholders   | \$                           | (20,825)        | \$ | (17,164)        | \$ | (15,675)          | \$ | (21,525)          |
| Basic and diluted net loss per share allocable to common stockholders   | \$                           | (0.11)          | \$ | (0.09)          | \$ | (0.09)            | \$ | (0.09)            |
| Shares used to compute basic and diluted net loss per share allocable to common                                 |                              |                 |    |                 |    |                   |    |                   |
| stockholders  |                              | 182,847         |    | 182,913         |    | 183,022           |    | 235,879           |
|   |                              |                 |    |                 |    |                   |    |                   |
|   | Year Ended December 31, 2012 |                 |    |                 |    |                   |    |                   |
|   |                              | Q1              |    | Q2              |    | Q3                |    | Q4                |
| Revenues  | \$                           | 2,350           | \$ | 2,684           | \$ | 2,874             | \$ | 1,806             |
| Net loss  | \$                           | (16,505)        | \$ | (15,110)        | \$ | (17,791)          | \$ | (20,543)          |
|   |                              |                 |    |                 | _  | (4 7 704)         | ď  | (20 E 42)         |
| Net loss allocable to common stockholders   | \$                           | (16,505)        | \$ | (15,110)        | \$ | (17,791)          | Ф  | (20,543)          |
| Net loss allocable to common stockholders Basic and diluted net loss per share allocable to common stockholders | \$<br>\$                     | (16,505) (0.11) |    | (15,110) (0.09) |    | (1/,/91) $(0.10)$ |    | (20,543) $(0.11)$ |
|   | -                            |                 |    |                 |    | . , ,             |    | ,                 |

## 17. Subsequent Events

In March, 2014 we announced a \$5.4 million milestone payment and amendment of our AstraZeneca agreement to transfer responsibility for all clinical development to AstraZeneca following conclusion of the ongoing Phase 1 clinical trial of AZD1419.

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

None.

#### 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 Principal 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 Principal Financial Officer, concluded that our disclosure controls and procedures are effective at the reasonable assurance level 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 Principal 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 (1992 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2013. 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.

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) (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 that 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, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013 of Dynavax Technologies Corporation and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California March 10, 2014

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

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control 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 1—Elections of Directors," "Executive Officers," "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Definitive Proxy Statement in connection with the 2014 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, 2013.

We have adopted the Dynavax Code of Conduct, a code of ethics that applies to our employees, including our Chief Executive Officer, Principal Financial Officer and to our non-employee directors. The Code of Conduct is publicly available on our website under the Investor Relations section at www.dynavax.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this report. If any substantive amendments are made to the Code of Conduct or any waiver granted, including any implicit waiver, from a provision of the Code of Conduct to our Chief Executive Officer or Principal Financial Officer, we will disclose the nature of such amendment or waiver on that website or in a report on Form 8-K. We will provide a written copy of the Dynavax Code of Conduct to anyone without charge, upon request written to Dynavax, Attention: Corporate Secretary, 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," "Director Compensation," "Compensation Discussion and Analysis," "Report of the Compensation Committee of the Board of Directors," and "Compensation Committee Interlocks and Insider Participation" 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 are 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 "Transactions with Related Persons" and "Independence of the Board of Directors" in the Proxy Statement.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

#### **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 Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

## 2. Financial Statement Schedules

Document

None, as all required disclosures have been made in the Consolidated Financial Statements and notes thereto or are not applicable.

## (b) Exhibits

Exhibit

Number

| Mullibel            | Document  |
|---------------------|---|
| 3.1(1)              | Sixth Amended and Restated Certificate of Incorporation.  |
| 3.2(1)              | Amended and Restated Bylaws   |
| 3.3(2)              | Form of Certificate of Designation of Series A Junior Participating Preferred Stock                         |
| 3.4(3)              | Certificate of Amendment of Amended and Restated Certificate of Incorporation                               |
| 3.5(4)              | Certificate of Amendment of Amended and Restated Certificate of Incorporation                               |
| 3.6(5)              | Certificate of Amendment of Amended and Restated Certificate of Incorporation                               |
| 3.7(6)              | Certificate of Designation of Series B Convertible Preferred Stock  |
| 4.1                 | Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above                                    |
| 4.2(7)              | Registration Rights Agreement, dated as of July 18, 2007, by and between the Company and Deerfield Entities |
| 4.3 <sup>(7)</sup>  | Form of Warrant to Purchase Common Stock  |
| 4.4(8)              | Form of Specimen Common Stock Certificate   |
| 4.5(2)              | Rights Agreement, dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC |
| 4.6(2)              | Form of Right Certificate   |
| 4.7(9)              | Form of Restricted Stock Unit Award Agreement under the 2004 Stock Incentive Plan                           |
| 4.8(10)             | Form of Warrant to Purchase Common Stock  |
| 4.9(11)             | Form of Warrant to Purchase Common Stock  |
| 4.11 <sup>(6)</sup> | Form of Specimen Preferred Stock Certificate  |
|                     |   |

| Exhibit<br>Number       | Document  |
|-------------------------|---|
| 10.30(13)†              | Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB  |
| 10.32(14)†              | License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company   |
| 10.38(9)+               | Form of Amended Management Continuity Agreement between the Company and certain of its executive officers   |
| 10.39†                  | Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and the Company  |
| 10.40(15)               | Amendment No. 2 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated February 3, 2009                               |
| 10.43(17)               | Equity Distribution Agreement, dated August 17, 2009, between the Company and Wedbush Morgan Securities, Inc.   |
| 10.44 <sup>(18)</sup>   | Amendment to Equity Distribution Agreement, dated September 10, 2009, between the Company and Wedbush Morgan Securities, Inc.   |
| 10.47 <sup>(10)</sup>   | Amended and Restated Purchase Option Agreement, dated November 9, 2009, between the Company and Symphony Dynamo Holding LLC and Symphony Dynamo, Inc.   |
| 10.48(10)               | Warrant Purchase Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC  |
| 10.49(10)               | Amended and Restated Registration Rights Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC  |
| 10.50 <sup>(10)</sup>   | Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between the Company and Symphony Dynamo Holdings LLC  |
| 10.54(20)               | Amendment No. 3 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated September 30, 2010                             |
| 10.55(21)               | First Amendment to Lease, dated as of May 21, 2004, between the Company and 2929 Seventh Street, LLC  |
| 10.56(21)               | Second Amendment to Lease, dated as of October 12, 2010, between the Company and 2929 Seventh Street, LLC   |
| 10.58 <sup>(22)</sup> + | Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010, by and between the Company and Dino Dina, M.D.   |
| 10.59(22)+              | Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010 by and between the Company and J. Tyler Martin, M.D.  |
| 10.61(23)+              | Form of Amended to Amended Management Continuity Agreement between the Company and certain of its executive officers  |
| 10.62(24)+              | 2011 Equity Incentive Plan  |
| 10.63(24)+              | Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan   |
| 10.64(24)+              | Form of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan   |
| 10.65(25)               | Third Amendment to Lease, dated as of April 1, 2011, between the Company and 2929 Seventh Street, LLC   |
| 10.66 <sup>(25)</sup>   | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, effective April 14, 2005, and amended April 6, 2011 |
| 10.67(26)†              | Amendment No. 4 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated September 23, 2011                             |
| 10.69(27)               | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, amended April 17, 2012                              |

| Exhibit<br>Number       | Document   |
|-------------------------|--|
| 10.70(28) +             | Employment Offer Letter to Christine R. Larson, dated August 1, 2012   |
| 10.72(29)               | Fourth Amendment to Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC   |
| 10.73(29)               | New Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC   |
| 10.74(29)               | Consulting Agreement, dated as of November 14, 2012, by and between the Company and Stanley A. Plotkin   |
| 10.75(29)+              | Amended and Restated Management Continuity and Severance Agreement, dated October 31, 2012, between the Company and J. Tyler Martin.                                   |
| 10.77(30)               | Consulting Agreement, dated as of March 29, 2013, by and between Solutio Partners and the Company  |
| $10.78^{(30+)}$         | Termination letter, dated as of March 29, 2013, by and between Stephen Tuck and the Company  |
| 10.79(31) +             | Employment Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company   |
| 10.80 <sup>(31)</sup> + | Management Continuity and Severance Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company  |
| 10.81(31) +             | Consulting Agreement, dated as of May 1, 2013, by and between Dino Dina, M.D. and the Company  |
| 10.82(32)               | At Market Issuance Sales Agreement, dated March 29, 2013, by and between the Company and MLV & Co. LLC   |
| 10.83                   | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, Amended February 4, 2014 |
| 10.84+                  | Employment Agreement, dated March 21, 2013, by and between David Novack and the Company  |
| 10.85+                  | Employment Agreement, dated July 11, 2013, by and between Robert Janssen, M.D. and the company   |
| 10.86+                  | Employment Agreement, dated February 5, 2014, by and between David L. Johnson and the Company  |
| 10.87†                  | Amendment No. 1 to the Agreement, dated December 15, 2008, by and between Glaxo Group Limited and the Company, dated December 13, 2013                                 |
| 10.88†                  | Amendment No. 5 to the Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated January 7, 2014  |
| 12.1                    | Statement of Computation of Ratio of Earnings to Fixed Charges   |
| 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 Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002   |
| 32.1*                   | Certification of Chief Executive Officer to Section 906 of the Sarbanes-Oxley Act of 2002  |
| 32.2*                   | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 101.INS                 | XBRL Instance Document   |
| 101.SCH                 | XBRL Taxonomy Extension Schema Document  |
| 101.CAL                 | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF                 | XBRL Taxonomy Extension Definition Linkbase  |
| 101.LAB                 | XBRL Taxonomy Extension Labels Linkbase Document   |
| 101.PRE                 | XBRL Taxonomy Extension Presentation Linkbase Document   |

The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-K), irrespective of any general incorporation language contained in such filing.

- (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 (File No. 000-50577) and such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on January 1, 2011.
- (2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K (File No. 000-50577), as filed with the SEC on November 6, 2008.
- (3) 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 January 4, 2010.
- (4) 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 January 5, 2011.
- (5) 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 May 30, 2013.
- (6) 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 November 1, 2013.
- (7) Incorporated by reference to Dynavax's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (8) Incorporated by reference to Dynavax's Registration Statement (File No. 333-109965) on Form S-1/A filed on January 16, 2004.
- (9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 000-50577), as filed with the SEC.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2009.
- (11) 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 April 13, 2010.
- (13) 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 (File No. 000-50577), as filed with the SEC.
- (14) 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 (File No. 000-50577), as filed with the SEC.
- (15) 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, 2009, as filed with the SEC.
- (17) 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 August 17, 2009.
- (18) 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, 2009, as filed with the SEC.
- (20) 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, 2010.
- (21) 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 13, 2010.
- (22) 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 November 23, 2010.
- (23) 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, 2011, as filed with the SEC.
- (24) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Registration Statement (File No. 333-171552) on Form S-8, as filed with the SEC on January 6, 2011.
- (25) 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, 2011, as filed with the SEC.
- (26) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2011.
- (27) 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, 2012, as filed with the SEC.

- (28) 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, 2012, as filed with the SEC.
- (29) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2012.
- (30) 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 April 4, 2013.
- (31) 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 May 3, 2013.
- (32) 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 March 29, 2013.
- † 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.
- + Indicates management contract or compensatory plan.

## **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 duly authorized, in the City of Berkeley, State of California.

Dynavax Technologies Corporation /s/ EDDIE GRAY **Eddie Gray Chief Executive Officer** (Principal Executive Officer) Date: March 10, 2014 By: /s/ MICHAEL OSTRACH **Michael Ostrach Vice President** (Principal Financial Officer) Date: March 10, 2014 By: /s/ DAVID JOHNSON **David Johnson** Vice President (Principal Accounting Officer)

Date: March 10, 2014

| <u>Signature</u>             | <u>Title</u>                   | <u>Date</u>    |
|------------------------------|--------------------------------|----------------|
| /s/ EDDIE GRAY               | Chief Executive Officer        | March 10, 2014 |
| Eddie Gray                   | (Principal Executive Officer)  |                |
| /s/ MICHAEL OSTRACH          | Vice President                 | March 10, 2014 |
| Michael Ostrach              | (Principal Financial Officer)  |                |
| /s/ DAVID JOHNSON            | Vice President                 | March 10, 2014 |
| David Johnson                | (Principal Accounting Officer) |                |
| /s/ ARNOLD L. ORONSKY, PH.D. | Chairman of the Board          | March 10, 2014 |
| Arnold L. Oronsky, Ph.D.     |                                |                |
| /s/ FRANCIS R. CANO, PH.D.   | Director                       | March 10, 2014 |
| Francis R. Cano, Ph.D.       |                                |                |
| /s/ DENNIS A. CARSON, M.D.   | Director                       | March 10, 2014 |
| Dennis A. Carson, M.D.       |                                |                |
| /s/ DINO DINA, MD.           | Director                       | March 10, 2014 |
| Dino Dina, M.D.              |                                |                |
| /s/ DENISE M. GILBERT, PH.D. | Director                       | March 10, 2014 |
| Denise M. Gilbert, Ph.D.     |                                |                |
| /s/ DANIEL L. KISNER, M.D.   | Director                       | March 10, 2014 |
| Daniel L. Kisner, M.D.       |                                |                |
| /s/ PEGGY V. PHILLIPS        | Director                       | March 10, 2014 |
| Peggy V. Phillips            |                                |                |
| /s/ STANLEY A. PLOTKIN, M.D. | Director                       | March 10, 2014 |
| Stanley A. Plotkin, M.D.     |                                |                |
| /s/ NATALE S. RICCIARDI      | Director                       | March 10, 2014 |
| Natale S. Ricciardi          |                                |                |

## EXHIBIT INDEX

| Exhibit<br>Number     | Document  Document  |
|-----------------------|---|
| 3.1(1)                | Sixth Amended and Restated Certificate of Incorporation.  |
| 3.2(1)                | Amended and Restated Bylaws   |
| 3.3(2)                | Form of Certificate of Designation of Series A Junior Participating Preferred Stock   |
| 3.4(3)                | Certificate of Amendment of Amended and Restated Certificate of Incorporation   |
| 3.5(4)                | Certificate of Amendment of Amended and Restated Certificate of Incorporation   |
| 3.6 <sup>(5)</sup>    | Certificate of Amendment of Amended and Restated Certificate of Incorporation   |
| 3.7 <sup>(6)</sup>    | Certificate of Designation of Series B Convertible Preferred Stock  |
| 4.1                   | Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above  |
| 4.2 <sup>(7)</sup>    | Registration Rights Agreement, dated as of July 18, 2007, by and between the Company and Deerfield Entities   |
| 4.3(7)                | Form of Warrant to Purchase Common Stock  |
| 4.4(8)                | Form of Specimen Common Stock Certificate   |
| 4.5(2)                | Rights Agreement, dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC   |
| 4.6(2)                | Form of Right Certificate   |
| 4.7 <sup>(9)</sup>    | Form of Restricted Stock Unit Award Agreement under the 2004 Stock Incentive Plan   |
| 4.8(10)               | Form of Warrant to Purchase Common Stock  |
| 4.9(11)               | Form of Warrant to Purchase Common Stock  |
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| 10.30(13)†            | Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB  |
| 10.32(14)†            | License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company   |
| 10.38(9)+             | Form of Amended Management Continuity Agreement between the Company and certain of its executive officers   |
| 10.39†                | Research and Development Collaboration and License Agreement, dated December 15, 2008, between Glaxo Group Limited and the Company                                  |
| 10.40(15)             | Amendment No. 2 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated February 3, 2009 |
| 10.43(17)             | Equity Distribution Agreement, dated August 17, 2009, between the Company and Wedbush Morgan Securities, Inc.   |
| 10.44 <sup>(18)</sup> | Amendment to Equity Distribution Agreement, dated September 10, 2009, between the Company and Wedbush Morgan Securities, Inc.                                       |
| 10.47 <sup>(10)</sup> | Amended and Restated Purchase Option Agreement, dated November 9, 2009, between the Company and Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.              |
| 10.48(10)             | Warrant Purchase Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC  |
| 10.49(10)             | Amended and Restated Registration Rights Agreement, dated as of November 9, 2009, between the Company and Symphony Dynamo Holdings LLC                              |

| Exhibit<br>Number       | Document  |
|-------------------------|---|
| 10.50(10)               | Standstill and Corporate Governance Agreement, dated as of December 30, 2009, between the Company and Symphony Dynamo Holdings LLC  |
| 10.54 <sup>(20)</sup>   | Amendment No. 3 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated September 30, 2010                             |
| 10.55(21)               | First Amendment to Lease, dated as of May 21, 2004, between the Company and 2929 Seventh Street, LLC  |
| 10.56(21)               | Second Amendment to Lease, dated as of October 12, 2010, between the Company and 2929 Seventh Street, LLC   |
| 10.58(22)+              | Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010, by and between the Company and Dino Dina, M.D.   |
| 10.59(22)+              | Amended and Restated Management Continuity and Severance Agreement, dated as of November 12, 2010 by and between the Company and J. Tyler Martin, M.D.  |
| 10.61(23)+              | Form of Amended to Amended Management Continuity Agreement between the Company and certain of its executive officers  |
| 10.62(24)+              | 2011 Equity Incentive Plan  |
| 10.63(24)+              | Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan   |
| 10.64(24)+              | Form of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan   |
| 10.65(25)               | Third Amendment to Lease, dated as of April 1, 2011, between the Company and 2929 Seventh Street, LLC   |
| 10.66(25)               | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, effective April 14, 2005, and amended April 6, 2011 |
| 10.67 <sup>(26)</sup> † | Amendment No. 4 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated September 23, 2011                             |
| 10.69(27)               | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, amended April 17, 2012                              |
| 10.70(28) +             | Employment Offer Letter to Christine R. Larson, dated August 1, 2012  |
| 10.72(29)               | Fourth Amendment to Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC  |
| 10.73(29)               | New Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC  |
| 10.74(29)               | Consulting Agreement, dated as of November 14, 2012, by and between the Company and Stanley A. Plotkin  |
| 10.75(29)+              | Amended and Restated Management Continuity and Severance Agreement, dated October 31, 2012, between the Company and J. Tyler Martin   |
| 10.77(30)               | Consulting Agreement, dated as of March 29, 2013, by and between Solutio Partners and the Company   |
| 10.78(30+)              | Termination letter, dated as of March 29, 2013, by and between Stephen Tuck and the Company   |
| 10.79(31) +             | Employment Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company  |
| 10.80 <sup>(31)</sup> + | Management Continuity and Severance Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company   |
| 10.81 <sup>(31)</sup> + | Consulting Agreement, dated as of May 1, 2013, by and between Dino Dina, M.D. and the Company   |
| 10.82(32)               | At Market Issuance Sales Agreement, dated March 29, 2013, by and between the Company and MLV & Co. LLC  |

| Exhibit<br>Number | Document   |
|-------------------|--|
| 10.83             | Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, Amended February 4, 2014 |
| 10.84+            | Employment Agreement, dated March 21, 2013, by and between David Novack and the Company  |
| 10.85+            | Employment Agreement, dated July 11, 2013, by and between Robert Janssen, M.D. and the company   |
| 10.86+            | Employment Agreement, dated February 5, 2014, by and between David L. Johnson and the Company  |
| 10.87†            | Amendment No. 1 to the Agreement, dated December 15, 2008, by and between Glaxo Group Limited and the Company, dated December 13, 2013                                 |
| 10.88†            | Amendment No. 5 to the Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated January 7, 2014  |
| 12.1              | Statement of Computation of Ratio of Earnings to Fixed Charges   |
| 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 Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002   |
| 32.1*             | Certification of Chief Executive Officer to Section 906 of the Sarbanes-Oxley Act of 2002  |
| 32.2*             | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 101.INS           | XBRL Instance Document   |
| 101.SCH           | XBRL Taxonomy Extension Schema Document  |
| 101.CAL           | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF           | XBRL Taxonomy Extension Definition Linkbase  |
| 101.LAB           | XBRL Taxonomy Extension Labels Linkbase Document   |
| 101.PRE           | XBRL Taxonomy Extension Presentation Linkbase Document   |

The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-K), irrespective of any general incorporation language contained in such filing.

- (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 (File No. 000-50577) and such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on January 1, 2011.
- (2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K (File No. 000-50577), as filed with the SEC on November 6, 2008.
- (3) 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 January 4, 2010.
- (4) 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 January 5, 2011.
- (5) 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 May 30, 2013.

- (6) 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 November 1, 2013.
- (7) Incorporated by reference to Dynavax's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (8) Incorporated by reference to Dynavax's Registration Statement (File No. 333-109965) on Form S-1/A filed on January 16, 2004.
- (9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 000-50577), as filed with the SEC.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2009.
- (11) 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 April 13, 2010.
- (13) 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 (File No. 000-50577), as filed with the SEC.
- (14) 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 (File No. 000-50577), as filed with the SEC.
- (15) 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, 2009, as filed with the SEC.
- (17) 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 August 17, 2009.
- (18) 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, 2009, as filed with the SEC.
- (20) 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, 2010.
- (21) 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 13, 2010.
- (22) 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 November 23, 2010.
- (23) 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, 2011, as filed with the SEC.
- (24) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Registration Statement (File No. 333-171552) on Form S-8, as filed with the SEC on January 6, 2011.
- (25) 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, 2011, as filed with the SEC.
- (26) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2011.
- (27) 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, 2012, as filed with the SEC.
- (28) 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, 2012, as filed with the SEC.
- (29) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Annual Report on Form 10-K, for the fiscal year ended December 31, 2012.
- (30) 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 April 4, 2013.
- (31) 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 May 3, 2013.
- (32) 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 March 29, 2013.

- † 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.
- + Indicates management contract or compensatory plan.

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

**EXHIBIT 10.39** 

RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT

BETWEEN

GLAXO GROUP LIMITED
AND
DYNAVAX TECHNOLOGIES CORPORATION

# RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT

This **RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT** (the "**Agreement**") is entered into and made effective as of the 15th day of December, 2008 (the "**Effective Date**") by and between Dynavax Technologies Corporation, a Delaware corporation having its principal place of business at 2929 Seventh Street, Suite 100, Berkeley, CA 94710 ("**Dynavax**"), and Glaxo Group Limited, a company existing under the laws of England and Wales, having its registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England ("**GSK**"). Dynavax and GSK are each referred to herein by name or as a "**Party**" or, collectively, as "**Parties.**"

## **RECITALS**

Whereas, Dynavax possesses proprietary technology and know-how related to the discovery, identification, synthesis and development of oligonucleotides as drug candidates;

Whereas, GSK possesses expertise in the research, development, manufacturing and commercialization of human pharmaceuticals, and GSK is interested in developing such oligonucleotides as drug products;

Whereas, GSK desires to engage in a collaborative effort with Dynavax pursuant to which Dynavax will carry out up to three (3) different research and development programs to discover and develop oligonucleotides as inhibitors of certain toll-like receptors (or combinations thereof), and pursuant to which GSK will have certain options, exercisable at GSK's sole discretion, to further develop and commercialize such oligonucleotides for any and all uses in the Territory (as defined below), all on the terms and conditions set forth herein.

**Now,** THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

## **ARTICLE 1**

## **DEFINITIONS**

As used in this Agreement, the following terms will have the meanings set forth in this Article 1 unless context dictates otherwise:

- **1.1** "Acceptance" means with respect to an NDA or MAA filed for a Product, (a) in the United States, the receipt by GSK or its Affiliate or Sublicensee of written notice from the FDA in accordance with 21 CFR 314.101(a)(2) that such NDA is officially "filed", (b) in the European Union, receipt by GSK or its Affiliate or Sublicensee of written notice of acceptance by the EMEA of such MAA for filing under the centralized European procedure in accordance with any feedback received from European Regulatory Authorities; provided, that if the centralized filing procedure is not used, then Acceptance shall be determined upon the acceptance of such MAA by the applicable Regulatory Authority in the third Major Country in the EU, and (c) in Japan, receipt by GSK or its Affiliate or Sublicensee of written notice of acceptance of filing of such MAA from the MHLW.
- **1.2 "Affiliate"** means any Person, whether *de jure* or *de facto*, which, directly or indirectly through one (1) or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.
  - **1.3 "Alliance Manager"** has the meaning assigned to such term in Section 3.2.
  - **1.4 "Annual Net Sales"** means total Net Sales in the Territory in a particular Calendar Year.
  - **1.5 "Arbitration Request"** has the meaning assigned to such term in Section 13.2.
  - **1.6** [\*] means that certain [\*], as amended from time to time.
- 1.7 "Back-up Compound" means, with respect to a lead Compound in a Dynavax Program, a Compound in such Dynavax Program that (i) may or may not be a [\*] to such lead Compound, (ii) has been or is expected to be advanced to the [\*] stage by Dynavax, (iii) is expected to reasonably address [\*] associated with such lead Compound, and (iv) is not a [\*].
  - **1.8 "Breaching Party"** has the meaning assigned to such term in Section 12.2.1.
- **1.9 "Business Day"** means a day on which banking institutions in New York, New York, United States, and London, England are open for business, excluding any Saturday or Sunday.

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- **1.10 "Calendar Day"** means any day, including a Saturday, Sunday, Business Day or public or company holiday.
- **1.11 "Calendar Quarter"** means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively.
  - 1.12 "Calendar Year" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31.
- 1.13 "cGMP" means all applicable standards relating to manufacturing practices for fine chemicals, intermediates, bulk products or Products, including (i) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 CFR Parts 210 and 211 and The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, as each may be amended from time to time or (ii) standards promulgated by any governmental body having jurisdiction over the manufacture of a Compound, in the form of laws or regulations.
  - **1.14 "Chairperson"** has the meaning assigned to such term in Section 3.1.1.
  - 1.15 "Change of Control Event" has the meaning assigned to such term in Section 13.4.
  - **1.16 "Claims"** has the meaning assigned to such term in Section 11.1.
  - 1.17 "Clinical Trial," means a Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, [\*] or Proof of Concept Study.
- **1.18 "Co-Development Costs"** means, with respect to a GSK Product, the sum of the following costs to the extent incurred after the exercise by GSK of an Option with respect to the GSK Development Program containing such GSK Product:
- **1.18.1** All direct internal and external Research and Development costs incurred by or on behalf of GSK or its Affiliates or Sublicensees or Dynavax and/or their respective Affiliates during such period in the conduct of the GSK Development Program (including but not limited to both Clinical Trials and any non-clinical activities or studies) that are required by a Regulatory Authority to support and obtain Regulatory Approval for such GSK Product in the U.S. (collectively, the **"Co-Development Studies"**), and for product material, comparator drug and placebo used in the Co-Development Studies.
- **1.18.2** Allocable overhead as included [\*], for [\*] costs described in Section 1.18.1, to the extent [\*] described in Section 1.18.1, where allocable overhead shall mean costs incurred by GSK or its Affiliates or Sublicensees or Dynavax or its Affiliates that are attributable to the costs of [\*] or such other generally accepted methods, in all cases as applied by the Party in accordance with its accounting standards on a consistent basis. Without limitation, allocable overhead shall not include the costs of [\*], including, by way of example, [\*].

Such costs as described in Section 1.18.1 and 1.18.2 shall be determined in accordance with applicable Generally Accepted Accounting Principles (GAAP) and in accordance with the Party's accounting standards applied on a consistent basis.

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- **1.19 "Co-Development Option"** has the meaning assigned to such term in Section 5.5.1(a).
- 1.20 "Collaboration IP" means the Collaboration Know-How and the Collaboration Patents.
- **1.21 "Collaboration Know-How"** means any Information pertaining to a Compound that is discovered, developed, invented or created solely by a Party or jointly by both Parties, or their respective agents, contractors, or Affiliates, during the Research Term and pursuant to a Dynavax Program, but prior to the earlier of GSK's exercise of the Option or expiration of the Option with respect to such Dynavax Program.
- **1.22 "Collaboration Patent"** means any Patent that claims or covers Collaboration Know-How that is not specifically disclosed, included, claimed or covered in the Dynavax Compound IP or the GSK Development IP.
- 1.23 "Commercially Reasonable Efforts" means the following: (a) with respect to Dynavax, such efforts that are consistent with the efforts and resources normally used by [\*] in the exercise of its reasonable business discretion relating to the research, development and commercial progression of a potential pharmaceutical product owned by it or to which it has exclusive rights, with similar product characteristics as the relevant Compound or Product, which is of similar market potential at a similar stage in its development or product life as the relevant Compound or Product, taking into account issues of patent coverage, safety and efficacy, product profile, competitiveness of the marketplace, proprietary position, [\*], and profitability (including pricing and reimbursement status achieved or likely to be achieved); and (b) with respect to GSK, such efforts that are consistent with the efforts and resources normally used by [\*] in the exerc ise of its reasonable business discretion relating to the development and commercialization of a prescription pharmaceutical product or over-the-counter product as appropriate owned by it or to which it has exclusive rights, with similar product characteristics as the relevant Compound or Product, which is of similar market potential at a similar stage in its development or product life as the relevant Compound or Product, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position, [\*] and profitability (including pricing and reimbursement status achieved or likely to be achieved).
  - **1.24 "Competitive Infringement"** has the meaning assigned to such term in Section 8.5.1.
- **1.25** "Compound" means each compound comprising an oligonucleotide-based immunoregulatory sequence ("IRS") that inhibits ([\*] unless otherwise mutually agreed by the JSC without escalation pursuant to Section 3.1.4) in a [\*] (such [\*] to be mutually agreed by the Parties through the JSC) for [\*] or [\*], as applicable for that Program, and all derivatives and improvements of such compound, (a) that are existing as of the Effective Date or (b) that are Researched and/or Developed by Dynavax under a Dynavax Program or (c) as identified, further modified, optimized or otherwise Researched or Developed by GSK under a GSK Development Program. In particular, for the TLR 7/9 directed compounds, the oligonucleotide-based IRS must have [\*] unless otherwise mutually agreed by the JSC without escalation pursuant to Section 3.1.4. For those Programs involving [\*], the JSC may establish criteria by mutual agreement for [\*] of a Compound with respect to [\*] TLR in such Program. For clarity, nothing in this Section 1.25 or elsewhere in this Agreement shall require Dynavax to measure the [\*].
  - **1.26 "Confidential Information"** has the meaning assigned to such term in Section 9.1.

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- **1.27 "Control," "Controls," "Controlled" or "Controlling"** means, with respect to any intellectual property, possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party. A Party shall be deemed to Control Collaboration IP to the extent of its individual or joint interest therein, as applicable.
  - **1.28 "Co-Promotion Agreement"** has the meaning assigned to such term in Section 5.5.2(a).
- **1.29 "Develop"** or **"Development"** means pre-clinical and clinical drug development activities relating to the development of Compounds, Products and/or processes and submission of information to a Regulatory Authority for the purpose of obtaining Regulatory Approval of a product, and activities to develop manufacturing capabilities for products. Development includes, but is not limited to, pre-clinical activities, pharmacology studies, toxicology studies, formulation, manufacturing process development and scale-up (including bulk compound production), manufacturing Compound or Product for Clinical Trials, quality assurance and quality control, technical support, pharmacokinetic studies, clinical studies and regulatory affairs activities.
  - **1.30 "Development Plan"** has the meaning assigned to such term in Section 2.2.
  - **1.31 "Disclosing Party"** has the meaning assigned to such term in Section 9.1.
  - **1.32 "Dollars"** or **"\$"** means the legal tender of the U.S.
- **1.33 "Dynavax Compound IP"** means Dynavax's and its Affiliates' interest in any: (a) Patents in the Territory that claim or cover the composition of matter or any method of making, use or sale of a Compound in the Field; and (b) Information that [\*] for the making, use or sale of a Compound in the Field, in each case to the extent such Patents or Information are Controlled by Dynavax or its Affiliates (i) on the [\*], or (ii) thereafter [\*] for any Patents which claim priority to any Patent filed during the Research Term. The Dynavax Compound IP excludes the Collaboration IP.
  - **1.34 "Dynavax Compound Patents"** means Patents in the Dynavax Compound IP.
- **1.35 "Dynavax Development Program"** means a Dynavax Program for which GSK fails to exercise its Option before expiration or GSK declines its Option, a Dynavax Program that is terminated by the JSC or GSK, or a terminated GSK Development Program containing Compounds and Products that Dynavax elects to further Develop and commercialize.
  - **1.36 "Dynavax Product"** means a Product Developed and commercialized by Dynavax under a Dynavax Development Program.
- **1.37 "Dynavax Program"** means Dynavax's Research and Development of Compounds through to either the [\*] or completion of a [\*] or Proof of Concept Study, as applicable. For clarity, there will be a maximum of [\*] potential Dynavax Programs under this Agreement, which shall be the TLR 7/9 Program [\*], each of which is subject to the relevant diligence provisions and milestones as if separate programs hereunder) and up to two (2) additional Dynavax Programs as identified pursuant to Section 2.5.
  - **1.38 "EMEA"** means the European Medicines Evaluation Agency, and any successor entity thereto.

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- **1.39** "European Commission" means the executive body of the European Union that has legal authority to grant marketing authorization approvals for pharmaceutical products in the European Union following scientific evaluation and recommendation from the EMEA or other applicable Regulatory Authorities.
- **1.40 "European Union"** or **"EU"** means all countries that are officially recognized as member states of the European Union at any particular time during the Term.
- **1.41 "Exclusively Licensed IP"** means, with respect to each Compound in a Dynavax Program for which GSK exercises the Option and receives rights upon exercise pursuant to Section 4.1, (a) Information in the Dynavax Compound IP and Dynavax's and its Affiliates' interest in the Collaboration Know-How, in each case that [\*] for the making, use or sale of such Compound [\*], and (b) Dynavax Compound Patents and Dynavax's and its Affiliates' interest in the Collaboration Patents, in each case that claims or covers the [\*] of such Compound.
  - **1.42 "Executive Officers"** has the meaning assigned to such term in Section 3.1.4.
  - 1.43 "FDA" means the U.S. Food and Drug Administration, and any successor entity thereto.
  - **1.44 "Field"** means [\*] the treatment, palliation, prevention and/or diagnosis of [\*].
- **1.45** "First Commercial Sale" means, with respect to each Product, the first sale for which revenue has been recognized by GSK or Dynavax or their respective Affiliate or Sublicensees for use or consumption by the general public of such Product in any country in the Territory after all required Regulatory Approvals (including, where applicable, pricing and reimbursement approval which is acceptable to GSK or Dynavax, as applicable depending upon which Party is going to be selling Product) have been granted, or such sale is otherwise permitted, by the Regulatory Authority in such country, provided, that, the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or Sublicensee unless the Affiliate or Sublicensee is the last entity in the distribution chain of the Product, (b) any use of such Product in Clinical Trials, preclinical activities or other Research or Development activities, or disposal or transfer of Products for a bona fide charitable purpose, (c) compassionate use, (d) so called "treatment IND sales" and "named patient sales," and (e) use under the ATU system in France or other equivalent systems.
  - 1.46 "[\*]" means a Compound in Development in the [\*] that (a) is or is reasonably expected to be [\*] and (b) has [\*].
  - 1.47 "[\*]" means the Research and Development, within the [\*], of [\*] to Compounds in the [\*].
  - **1.48 "FTC"** has the meaning assigned to such term in Section 4.1.5.
- **1.49 "FTE"** means a full-time individual's work time dedicated by Dynavax to the Dynavax Programs or by GSK to the GSK Development Programs, or in the case of less than a full-time dedicated individual, a full-time equivalent person year, based upon a total of [\*] hours per year of Research, Development, manufacturing and commercialization work on or directly related to the Dynavax Programs or GSK Development Programs.

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- **1.50** "Generic Product" has the meaning assigned to such term in Section 6.4.2(b).
- **1.51** "GSK Development Compound" means any Compound, including Back-up Compounds, within a Dynavax Program that has become a GSK Development Program upon GSK's exercise of the Option.
- **1.52** "GSK Development IP" means any (a) Patents that claim or cover the composition of matter of a GSK Development Compound or GSK Product or the making, use, sale, [\*] of a GSK Development Compound or GSK Product; and (b) any Information that [\*] of a GSK Development Compound or GSK Product [\*], in each case to the extent such Patents or Information are Controlled by GSK or its Affiliates, but excluding any Collaboration IP and any Dynavax Compound IP or Exclusively Licensed IP.
  - **1.53 "GSK Development Patent"** has the meaning assigned to such term in Section 8.2.2.
  - 1.54 "GSK Development Plan and Budget" has the meaning assigned to such term in Section 5.5.1(a).
  - **1.55** "GSK Development Program" means a Dynavax Program for which GSK exercises its Option and that has not been terminated by GSK.
  - 1.56 "GSK Product" means a Product Developed and commercialized by GSK or its Affiliate or Sublicensee under a GSK Development Program.
  - **1.57 "HSR"** has the meaning assigned to such term in Section 4.1.5.
- **1.58 "IND"** means an investigational new drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. (such as a clinical trial application in the European Union).
  - **1.59 "Indemnitee"** has the meaning assigned to such term in Section 11.3.
- **1.60 "Information"** means all tangible and intangible (a) information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, data, results (including pharmacological, toxicological and clinical test data and results, and Research or Development data, reports and batch records), analytical and quality control data, analytical methods (including applicable reference standards), full batch documentation, packaging records, release, stability, storage and shelf-life data, and manufacturing process information, results or descriptions, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material. As used in this Section 1.60, "**clinical test data**" shall be deemed to include all information related to the clinical or pre-clinical testing of a Compound or Product, including without limitation patient report forms, investigators' reports, biostatistical, pharmaco-economic and other related analyses, regulatory filings and communications, and the like.
  - **1.61 "Joint Steering Committee"** or "JSC" has the meaning assigned to such term in Section 3.1.
  - **1.62 "Know-How Royalty"** has the meaning assigned to such term in Section 6.4.2(a).

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- **1.63** "[\*]" means the research and development of [\*], as of the Effective Date, in the TLR 7/9 Program and its Back-up Compounds.
- **1.64 "Losses"** has the meaning assigned to such term in Section 11.1.
- **1.65 "Major EU Country"** means any of the [\*].
- **1.66 "MAA"** means a regulatory application filed with the EMEA or MHLW seeking Regulatory Approval of a Product, and all amendments and supplements thereto filed with the EMEA or MHLW.
  - **1.67 "Materials"** has the meaning assigned to such term in Section 2.10.
- **1.68 "MHLW"** means the Ministry of Health, Labour and Welfare of Japan, or the Pharmaceuticals and Medical Devices Agency (the "PMDA," formerly known as IYAKUHIN SOGO KIKO), or any successor to either of them, as the case may be.
- **1.69 "NDA"** means a New Drug Application (as more fully defined in 21 C.F.R. 314.5 *et seq.* or its successor regulation) and all amendments and supplements thereto filed with the FDA.
- 1.70 "Net Sales" means, with respect to any Product, the gross invoiced sales price of such Product sold by GSK or Dynavax or their respective Affiliates or Sublicensees (the "Selling Party") in finished product form, packaged and labeled for sale, under this Agreement in arm's length sales to Third Parties, less deductions allowed to the Third Party customer by the Selling Party and actually incurred, allowed, paid, accrued or specifically allocated as reported by the Selling Party in its financial statements in accordance with the International Financial Reporting Standards ("IFRS") for GSK (or any other Selling Party which accounts in accordance with IFRS) or US (as appropriate) Generally Accepted Accounting Principles for Dynavax (or any other Selling Party which accounts in accordance with US or UK (as appropriate) Generally Accepted Accounting Principles), applied on a consistent basis, for:
- **1.70.1** customary and reasonable trade, quantity, and cash discounts and wholesaler allowances; provided that, in the case of pharmacy incentive research programs, hospital performance incentive research program chargebacks, disease management research programs, similar research programs or discounts and wholesaler allowances on "bundles" of products, all discounts, wholesaler allowances and the like shall be [\*];
- 1.70.2 customary and reasonable credits, rebates and chargebacks (including those to managed-care entities and government agencies), and allowances or credits to customers on account of rejection or returns (including, but not limited to, wholesaler and retailer returns) or on account of retroactive price reductions affecting such Product;
  - 1.70.3 freight, postage and duties, and transportation charges relating to such Product, including handling and insurance thereto;

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**1.70.4** sales (such as VAT or its equivalent) and excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities and any other governmental charges imposed upon the importation, use or sale of such Product to Third Parties (excluding any taxes paid on the income from such sales) to the extent the Selling Party is not otherwise entitled to a credit or a refund for such taxes, duties or payments made;

1.70.5 [ \* ]; and

**1.70.6** other items actually deducted from gross sales in relation to changes in accounting guidelines as per IFRS and to the extent that such deductions are consistently applied across the relevant Party's business.

Sales between GSK and its Affiliates or Sublicensees, or Dynavax and its Affiliates or Sublicensees, as applicable, shall be excluded from the computation of Net Sales, and no payments will be payable on such sales except where such Affiliate or Sublicensee is the last entity in the distribution chain for the Product and is purchasing it for its own commercial use, in which case such sales shall be deemed to be at [\*]. In addition, Product provided to patients for compassionate use will not be included in Net Sales. [\*].

For purposes of determining Royalties and sales milestones payable on Combination Products, Net Sales will be calculated as follows, in each calendar quarter:

In the event that Compound is sold as part of a Combination Product (as defined below), the Net Sales from the Combination Product will be determined by multiplying the Net Sales (as determined without reference to this paragraph) of the Combination Product by the fraction [\*], where [\*] is the [\*] of the Compound [\*] when sold separately in finished form and [\*] is the [\*] of the other therapeutically active pharmaceutical compound(s) included in the Combination Product when sold separately in finished [\*], each during the applicable royalty period or, if sales of all compounds did not occur in such period, then [\*]. In the event that such [\*] cannot be determined for both the Compound and all other therapeutically active pharmaceutical compounds included in the Combination Product [\*], Net Sales for the purposes of determining royalty payments will be calculated as above, but the [\*] in the above equation will be replaced by [\*] of the compound(s) for which no such price exists. As used above, the term "Combination Product" shall mean any pharmaceutical product which contains a Compound together with at least one other therapeutically active pharmaceutical compound (whether or not coformulated or co-packaged with the Compound in such Product) which is not a Compound. To be a Combination Product, products must be invoiced as one product. Notwithstanding the foregoing, drug delivery vehicles, adjuvants and excipients shall not be deemed to be active pharmaceutical compounds and their presence shall not be deemed to create a Combination Product. [\*].

To the extent the Net Sales is used herein with respect to Dynavax Products, Net Sales shall have the meaning set forth above, with all references to "GSK" replaced by "Dynavax."

- **1.71 "Non-breaching Party"** has the meaning assigned to such term in Section 12.2.1.
- **1.72** "[\*]" has the meaning assigned to such term in Section 2.8.
- **1.73** "Option" has the meaning assigned to such term in Section 4.1.1.

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- **1.74 "Option Deadline Extension Period"** has the meaning assigned to such term in Section 4.1.5.
- **1.75 "Option Deadline Period"** has the meaning assigned to such term in Section 4.1.5.
- **1.76 "Option Period Start"** has the meaning assigned to such term in Section 4.1.2.
- **1.77 "Party" or "Parties"** has the meaning assigned to such term in the Preamble.
- **1.78 "Patent"** means (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, (b) any substitutions, divisions, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.
- **1.79 "Patent Costs"** means the reasonable fees and expenses paid to outside legal counsel, and filing, maintenance and other out-of-pocket expenses paid to Third Parties, incurred in connection with the Prosecution and Maintenance of Patents.
  - **1.80 "Patent Royalty"** has the meaning assigned to such term in Section 6.4.1.
  - **1.81 "Payee"** has the meaning assigned to such term in Section 6.9.
  - **1.82 "Payor"** has the meaning assigned to such term in Section 6.9.
- **1.83 "Person"** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
- **1.84 "Phase 1 Clinical Trial"** means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.
- **1.85 "Phase 2 Clinical Trial"** means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.
- **1.86 "Phase 3 Clinical Trial"** means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

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- **1.87 "Phase I Ready Compound"** means a Compound (including all Back-up Compounds if progressed to this stage) from a Dynavax Program that has met the applicable Phase I Ready Criteria, or is [\*] such criteria.
- **1.88 "Phase I Ready Criteria"** means the clinical and/or non-clinical criteria (a) set forth in <u>Exhibit C</u> and as modified by the JSC [\*] for the [\*] TLR 7/9 Program and (b) established and as modified by the JSC pursuant to Section 2.6.2 for the other Dynavax Programs (including the [\*]), for advancement of a Pre-Candidate Selection Compound from a Dynavax Program into clinical Development. In general, Phase I Ready Criteria for a particular Compound will be reasonable and appropriate for [\*] and generally may include: [\*].
  - **1.89 "Phase I Ready Report"** has the meaning assigned to such term in Section 2.7.2.
- **1.90 "Pre-Candidate Selection Criteria"** means the criteria established by the JSC pursuant to Section 2.6.1 for [\*] in the [\*] TLR 7/9 Program and for Compounds in the [\*] and the other Dynavax Programs, for advancement of a Compound from a Dynavax Program into IND-enabling studies. In general, the Pre-Candidate Selection Criteria for a particular Compound will be reasonable and appropriate for [\*] and may include [\*].
  - **1.91** "Pre-Candidate Selection Report" has the meaning assigned to such term in Section 2.7.1.
  - **1.92 "Product"** means any product that includes a Compound, whether or not as the sole active ingredient and in any dosage form or formulation.
  - **1.93 "Product Marketing Plan"** has the meaning assigned to such term in Section 5.5.2.
  - **1.94 "Program"** means a Dynavax Program, Dynavax Development Program, or GSK Development Program, as applicable.
- **1.95 "Proof of Concept"** or **"PoC"** means the stage of Development at which a Phase I Ready Compound has successfully satisfied the Proof of Concept Criteria, as such criteria are determined by GSK.
- **1.96 "Proof of Concept Criteria"** means the clinical and/or non-clinical criteria established [\*], pursuant to Section 2.6.5 and in accordance with the guidelines attached hereto as <u>Exhibit D</u>, to determine whether a Phase I Ready Compound demonstrates [\*]. This shall include [\*] and any other reasonable parameters. The Proof of Concept Criteria shall include, without limitation, [\*]. The criteria may be different for each Dynavax Program.
- **1.97 "Proof of Concept Study"** means a human clinical trial for a particular Phase I Ready Compound that meets the requirements of 21 C.F.R. Section 312.21(b) and is intended to explore [\*].
  - **1.98 "Proof of Concept Study Design"** or **"PoC Study Design"** means the design, content and endpoints for a Proof of Concept Study.
  - **1.99 "Proof of Concept Study Report"** or "PoC Study Report" has the meaning assigned to such term in Section 2.7.4.

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- 1.100 "[\*]" or "[\*]" means the stage of Development at which a Phase I Ready Compound has successfully satisfied the [\*] Criteria, as such criteria are determined by [\*].
- **1.101 "[\*] Criteria"** means the criteria established by **[\*]** pursuant to Section 2.6.3 and in accordance with the guidelines attached hereto as Exhibit E.
- 1.102 "[ \* ]" or "[ \* ] Study" means a study performed in humans in order to [ \* ] of a particular Phase I Ready Compound in humans and to guide [ \* ].
  - 1.103 "[\*] Design" or "[\*] Study Design" means the design, content and endpoints for a [\*].
  - **1.104** "[\*] **Report**" or "[\*] **Study Report**" has the meaning assigned to such term in Section 2.7.3.
  - **1.105 "Prosecuting Party"** has the meaning assigned to such term in Section 8.2.3.
- **1.106 "Prosecution and Maintenance"** or **"Prosecute and Maintain"** means, with regard to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, as well as re-examinations, reissues, and requests for patent term adjustments and patent term extensions with respect to such Patent, together with the initiation or defense of interferences, the initiation or defense of oppositions and other similar proceedings with respect to the particular Patent, and any appeals therefrom. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" shall not include any other enforcement actions taken with respect to a Patent.
  - **1.107 "Receiving Party"** has the meaning assigned to such term in Section 9.1.
- **1.108 "Regulatory Approval"** means any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other government entity that are necessary for the manufacture, use, storage, import, transport and/or sale of a particular Product in the applicable jurisdiction.
- **1.109 "Regulatory Authority"** means the FDA in the U.S. or any health regulatory authority in another country in the Territory that is a counterpart to the FDA and holds responsibility for granting regulatory marketing approval for a Product in such country, including the European Commission and the MHLW, and any successor(s) thereto.
- **1.110 "Research"** means the discovery, identification, research, characterization, modification, derivatization, optimization, and pre-clinical testing of pharmaceutical compounds.
  - **1.111 "Research Term"** has the meaning assigned to such term in Section 2.3.
  - **1.112 "Senior Executive Officers"** has the meaning assigned to such term in Section 5.1.2.
  - **1.113 "Subcommittee"** has the meaning assigned to such term in Section 3.1.7.

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- **1.114 "Sublicensee"** means, with respect to a particular Product, a Third Party to whom GSK or Dynavax, as applicable, has granted a sublicense or license under any Dynavax Compound IP and/or Collaboration IP and/or Exclusively Licensed IP and/or GSK Development IP licensed to such Party pursuant to this Agreement, but excluding any Third Party acting solely as a distributor.
  - 1.115 "[ \* ]" means [ \* ].
  - **1.116** "[\*]" means that certain [\*], as amended from time to time, to the extent pertaining to [\*] of TLRs.
  - 1.117 "Term" has the meaning assigned to such term in Section 12.1.
  - **1.118 "Territory"** means the entire world.
  - 1.119 "Third Party" means any entity other than Dynavax or GSK or an Affiliate of Dynavax or GSK.
  - **1.120 "TLR"** means any of the human toll-like receptors [\*], [\*], [\*] and [\*].
- **1.121 "TLR 7/9 Program"** means, collectively, the Dynavax Program directed toward the discovery, Research and Development of Compounds that inhibit both TLR 7 and TLR 9, [\*].
  - 1.122 "United States" or "U.S." means the United States of America and all of its territories and possessions.
- **1.123 "Valid Claim"** means any claim within a pending ([\*]), allowed or issued U.S. patent application or patent, or pending, accepted or issued patent application or patent in a jurisdiction outside the U.S., that has not expired, lapsed, been cancelled or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including without limitation through opposition, reexamination, reissue or disclaimer.

## **ARTICLE 2**

## RESEARCH AND DEVELOPMENT

**2.1 Overview**. Pursuant to this Agreement and as further provided in this Article 2, Dynavax will undertake the TLR 7/9 Program and, if identified and agreed pursuant to Section 2.5, one (1) or two (2) additional Dynavax Programs under the supervision of the JSC during the Research Term. The objective of the Dynavax Programs is the identification, optimization, Research and Development of Compounds, which Compounds GSK shall have Options to exclusively license on a worldwide basis, as provided in Article 4.

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- 2.2 Development Plans. Each Dynavax Program will be carried out by Dynavax pursuant to a development plan (each, a "Development Plan") that will outline anticipated Research and Development activities to be conducted by Dynavax and [\*]. Any estimates regarding [\*] shall be intended as a general guide only, and Dynavax shall continue to progress each Dynavax Program with Commercially Reasonable Efforts, even if Commercially Reasonable Efforts would require a [\*] set forth in the Development Plan. The initial Development Plan for the [\*] TLR 7/9 Program has been agreed to by the Parties and is attached hereto as Exhibit A. Development Plans for the other Dynavax Programs will be prepared in accordance with Section 2.5. The Development Plan for the [\*] will be prepared within [\*] after the Effective Date, unless otherwise agreed by the JSC. From time to time during the Research Term [\*], Dynavax shall update each Development Plan (or applicable portion thereof) and shall submit such updated Development Plan to the JSC for review and comment. Dynavax shall consider all such comments in good faith before preparing an updated Development Plan, however each such Development Plan will be designed with the objective of enabling a determination upon completion of the Development Plan as to whether all of the criteria (either Pre-Candidate Selection Criteria, Phase I Ready Criteria, [\*] Criteria or PoC Criteria) have been met. Each updated Development Plan shall replace the Development Plan previously in effect. Each Development Plan will be reviewed as necessary at each meeting of the JSC, and at any other time upon the request of either Party, and the JSC may suggest modifications, as appropriate, to reflect material scientific or commercial developments. In the event of any inconsistency between any Development Plan and this Agreement, the terms of this Agreement shall prevail and any such inconsistent portion of a Development Plan is hereby expressly rejected.
- **2.3 Research Term.** The Research term shall commence on the Effective Date and shall expire five (5) years thereafter (the "**Initial Research Term**"), subject to extension (a) for up to [\*] of the Parties, or (b) [\*] no later than [\*] prior to expiration of the Initial Research Term, if [\*], as applicable, before the expiration of the Initial Research Term (as may be extended, the "**Research Term**"), and in such case, the Research Term shall be extended [\*].

## 2.4 Dynavax Programs.

**2.4.1** *Dynavax Responsibility.* Prior to GSK's exercise of an Option with respect to a Dynavax Program, Dynavax shall have primary responsibility for the Research and Development of each Compound (including, but not limited to, clinical trials and submissions to regulatory agencies) under such Dynavax Program in accordance with the applicable Development Plan. Subject to Sections 2.6.4 and 2.6.6, Dynavax shall be solely responsible for all internal and external expenses in connection with the Dynavax Programs. Subject to Section 5.2, Dynavax's obligation to conduct each Dynavax Program shall terminate at the earlier of (a) GSK's exercise of the Option with respect to such Dynavax Program, (b) expiration of the Research Term, as may be extended pursuant to Section 2.3, or (c) [\*] decision to terminate such Dynavax Program.

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**2.4.2** *Diligence.* The objective of each Dynavax Program is to discover and Develop [\*] and, if applicable under [\*], Compounds satisfying the Proof of Concept Criteria or [\*] Criteria, as applicable. During the Research Term, Dynavax shall use Commercially Reasonable Efforts to conduct each Dynavax Program and related Research and Development activities for such Dynavax Program in accordance with the applicable Development Plan. In particular and without limiting the generality of the foregoing, and subject to Sections 2.6.4 and 2.6.6, for each Dynavax Program, Dynavax shall use Commercially Reasonable Efforts to conduct Research and Development activities to identify [\*] that satisfy the [\*] for each Dynavax Program and, if determined pursuant to [\*], progress [\*] through to either (i) completion of a [\*] Study in an effort to achieve the [\*] Criteria, or (ii) completion of a Proof of Concept Study in an effort to achieve the Proof of Concept Criteria, as determined pursuant to Section 2.6.5.

**2.4.3** *TLR 7/9 Program.* The TLR 7/9 Program shall include efforts to discover, Research and Develop Compounds for [\*] dual inhibitors of TLR 7 and TLR 9.

**2.4.4** *GSK Research Activities.* GSK shall, upon Dynavax's request, consult with Dynavax regarding the Research and Development of Compounds under each Dynavax Program. On a Dynavax Program-by-Dynavax Program basis, the Parties shall discuss and consider in good faith [\*], prior to GSK's exercise of an Option with respect to such Dynavax Program in order to [\*]. Dynavax shall [\*].

**2.5 Identification of Additional Programs.** [\*] may propose to the JSC up to two (2) additional Dynavax Programs to be conducted by Dynavax during the [\*]. Upon GSK's request during the [\*] of the [\*], GSK and Dynavax will identify and agree upon, through the JSC, such additional two (2) Dynavax Programs to include under this Agreement, which during the [\*] of the [\*], would involve Research and Development of inhibitors of [\*], and during the [\*] of the [\*], would involve Research and Development of inhibitors of [\*]. If the JSC cannot reach consensus on the selection of one or both of such additional Dynavax Programs, then [\*] in accordance with Section 3.1.4(c). Promptly after each such Dynavax Program is selected, Dynavax shall prepare a Development Plan for such Program for submission to the JSC for review and comment. Dynavax shall consider all such comments in good faith before finalizing such Development Plan, after which Dynavax shall promptly commence and conduct such Program with its Commercially Reasonable Efforts.

## 2.6 Compound Criteria; [\*] and Proof of Concept Study Designs.

**2.6.1** *Pre-Candidate Selection Criteria.* The JSC shall establish the Pre-Candidate Selection Criteria for each Dynavax Program within (a) [\*] of the Effective Date for Back-up Compounds in the [\*] TLR 7/9 Program and for the [\*], or (b) [\*] of the identification of each other Dynavax Program under Section 2.5. Such Pre-Candidate Selection Criteria shall be consistent with the generic criteria attached in <u>Exhibit B</u>, modified as necessary by mutual agreement of the JSC [\*].

**2.6.2** *Phase I Ready Criteria*. As of the Effective Date, the Parties have agreed upon the Phase I Ready Criteria for the [\*] TLR 7/9 Program, which criteria may be modified by mutual agreement of the JSC [\*]. The JSC shall establish the Phase I Ready Criteria for the [\*] within [\*] TLR 7/9 Program. Within [\*] after the identification of a Dynavax Program under Section 2.5, the JSC shall establish Phase I Ready Criteria for such Dynavax Program, which shall be substantially similar to the example of Phase I Ready Criteria set forth in Exhibit C.

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**2.6.3** [\*] *Criteria*. Prior to the determination by the JSC of a Phase 1 Ready Compound for a given Dynavax Program, GSK or Dynavax may propose that Dynavax [\*] for such Program, by submitting to the JSC proposed [\*] Criteria and [\*] Study Design that are reasonably consistent with the guidelines attached hereto as Exhibit E. The JSC shall consider such proposal and determine, [\*], whether such Dynavax Program will include a [\*]. Promptly following a decision by the JSC to conduct a [\*] Study, but in no event later than [\*] over the [\*] Criteria.

2.6.4 [\*] Design. The JSC shall be responsible for establishing the [\*] Design for each Dynavax Program for which a [\*] Study will be conducted. Notwithstanding [\*] with respect to the [\*] Study Design, as set forth in Section 3.1.4(c), in no event shall Dynavax be obligated to [\*] for any single [\*] Study and all Development activities required specifically for such [\*] Study. In the event that the [\*] Study conducted in accordance with the applicable [\*] Study Design and Development Plan, and all Development activities required specifically for such [\*], except to the extent due to [\*]. In the event that Dynavax [\*] for a PoC Study and all Development activities required specifically for such PoC Study, [\*], as such PoC Study and all Development activities required specifically for such [\*] Study and all Development activities required specifically for such [\*] Study and all Development activities required specifically for such [\*] Study against [\*] for such Dynavax Program after the completion of such [\*] Study. In the event that Dynavax [\*] of [\*] for any single [\*] Study and all Development activities required specifically for such [\*] Study. In the event that Dynavax [\*] of [\*] for any single [\*] Study and all Development activities required specifically for such [\*] Study and all Development activities required specifically for such [\*] Study in the preceding Calendar Quarter. [\*] of such [\*] Study [\*] of each milestone set forth in Sections [\*], up to a [\*] of [\*]. In any event, Dynavax shall be obligated to complete any [\*] Study [\*] pursuant to this Section 2.6.4.

**2.6.5** *Proof of Concept Criteria.* Prior to the initiation of the first applicable [\*] for a Program, [\*] shall establish the provisional clinical trial design, including planned [\*], for the Proof of Concept Study, and shall [\*], collectively, as the Proof of Concept Criteria, prior to initiation of the PoC Study. All such Proof of Concept Criteria shall be established reasonably in accordance with the guidelines and examples attached hereto as <u>Exhibit D</u>.

**2.6.6** *PoC Study Design.* The JSC shall be responsible for [\*] for each Dynavax Program. Notwithstanding [\*] with respect to the PoC Study Design, as set forth in Section 3.1.4(c), in no event shall Dynavax be obligated to [\*] of [\*] for any single Proof of Concept Study and all Development activities required specifically for such Proof of Concept Study. In the event that the [\*] for any Proof of Concept Study conducted in accordance with the applicable PoC Study Design and Development Plan, and all Development activities required specifically for such Proof of Concept Study, [\*], then [\*], except to the extent due to [\*] within [\*] after [\*] provided by Dynavax setting forth the [\*] for such Proof of Concept Study in the preceding Calendar Quarter. [\*] of such [\*] against [\*] of each milestone set forth in Sections 6.2.1 and 6.2.2, up to a [\*] of [\*]. In any event, Dynavax shall be obligated to complete any PoC Study funded by GSK pursuant to this Section 2.6.6.

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## 2.7 Evaluation of Pre-Candidate Selection Criteria, Phase I Ready Criteria, [\*] Criteria and Proof of Concept Criteria.

**2.7.1** *Pre-Candidate Selection Criteria*. In the event that a Compound achieves [\*] of the Pre-Candidate Selection Criteria after Dynavax has completed the activities required to make such an assessment, it being understood by the Parties that drug discovery is an iterative problemsolving process and that multiple Compounds may be expected to be progressed in order to identify a Compound that merits advancement into IND-enabling studies, Dynavax shall promptly notify GSK in writing of such event and shall provide to the JSC a completed data package containing the complete set of the analyses, results and raw data from the Dynavax Program for such Compound (the "**Pre-Candidate Selection Report**"). Unless otherwise agreed to by the Parties, the JSC will schedule an ad hoc meeting not more than [\*] after receipt by GSK's JSC representatives of such complete Pre-Candidate Selection Report to review such Pre-Candidate Selection Report and to confirm whether or not such Compound meets [\*] of the Pre-Candidate Selection Criteria. In the event that the JSC agrees that all or substantially all of the Pre-Candidate Selection Criteria have been met, [\*], and Dynavax shall use its Commercially Reasonable Efforts to continue to progress the Dynavax Program through to completion of the PoC Study or [\*] Study, as applicable, subject to Section 2.7.2 below. If the JSC fails to agree that [\*] of the Pre-Candidate Selection Criteria have been met, then the matter shall be resolved by [\*] determines that all or substantially all of the Pre-Candidate Selection Criteria have been met, then the [\*], and Dynavax shall use its Commercially Reasonable Efforts to continue to progress the Dynavax Program through to completion of the PoC Study or [\*] Study, as applicable under the relevant provisions of Articles 2 and 3. [\*] of the Pre-Candidate Selection Criteria have been met, then Dynavax shall complete any additional studies as are [\*] Pre-Candidate Selection Criteria and progress such Compound through completion of the PoC study or [\*] Study, as applicable under the relevant provisions of Articles 2 and 3. If the achievement of such criteria is [\*], Dynavax shall instead progress a Backup Compound in place of the Compound that failed to meet the criteria, and Dynavax shall use its Commercially Reasonable Efforts to progress such Backup Compound through to completion of the PoC Study or [\*] Study, as applicable under the relevant provisions of Articles 2 and 3.

**2.7.2** *Phase I Ready Criteria*. In the event that a Compound achieves [\*] of the Phase I Ready Criteria after Dynavax has completed the activities required to make such an assessment, it being understood by the Parties that drug discovery is an iterative problem-solving process, and that multiple Compounds may be expected to be progressed in order to identify a Compound that merits advancement into clinical Development, Dynavax shall promptly notify GSK in writing of such event and shall provide to the JSC a complete data package containing all analyses, results and raw data from the Dynavax Program for such Compound (the "**Phase I Ready Report**"). Unless otherwise agreed to by the Parties, the JSC will schedule an ad hoc meeting not more than [\*] after receipt by GSK's JSC representatives of any such complete Phase I Ready Report to review such Phase I Ready Report and to confirm whether or not such Compound meets [\*] of the Phase I Ready Criteria.

(a) If the JSC agrees that such Compound has achieved [\*] of the Phase I Ready Criteria, then if such Compound is [\*], the Parties shall determine whether GSK shall [\*] as to such Dynavax Program pursuant to [\*].

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**(b)** If the JSC fails to agree that the Compound has satisfied [\*] of the Phase I Ready Criteria, then the matter shall be resolved by [\*] of the Phase I Ready Criteria have been met, then Dynavax shall complete any additional studies as are necessary [\*] the Phase I Ready Criteria and progress such Compound through completion of the PoC study or [\*] Study, as applicable under the relevant provisions of Articles 2 and 3. If the achievement of such criteria is not [\*], Dynavax shall instead progress a Backup Compound in place of the Compound that failed to meet the criteria, and Dynavax shall use its Commercially Reasonable Efforts to progress such Backup Compound through to completion of the PoC Study or [\*] Study, as applicable under the relevant provisions of Articles 2 and 3.

(c) If either (i) the JSC agrees that such Compound has [\*] of the Phase I Ready Criteria, and GSK either [\*] in accordance with the applicable provisions of this Agreement, or (ii) [\*] of the Phase I Ready Criteria, and GSK either [\*] in accordance with the applicable provisions of this Agreement, then Dynavax shall progress such Compound into a Phase 1 Clinical Trial [\*]. A Compound that either the JSC, [\*] of the Phase I Ready Criteria shall be considered to be at the "Phase I Ready" stage.

**2.7.3** [\*] Criteria. Upon the completion of any [\*] Study, Dynavax shall promptly notify GSK in writing of such event and shall provide to the JSC a complete data package containing all analyses, results and raw data from the completion of the [\*] Study for such Phase I Ready Compound, and any related correspondence and information received from or sent to any Regulatory Authority relating to such Phase I Ready Compound (the "[\*] Study Report"). GSK shall [\*] upon the completion of the [\*] Study pursuant to [\*]. Unless otherwise agreed by the Parties, if requested by GSK, the JSC will schedule an ad hoc meeting not more than [\*] after receipt of any such [\*] Study Report to review such [\*] Study Report and confirm whether or not such Phase I Ready Compound satisfies the [\*] Criteria. If the JSC (or the Executive Officers or GSK pursuant to Section 3.1.4(c)) decides that the Phase I Ready Compound did not satisfy the [\*] Criteria, then, except as provided in Section 5.3, [\*] with respect to such Dynavax Program and GSK [\*] with respect to such Dynavax Program at [\*]. In the event that the Compound fails to satisfy the [\*] Criteria after completion of the [\*] Study, but GSK [\*] to such Dynavax Program, and GSK determines to [\*] Study, in such case [\*] for such GSK Development Program shall all be [\*] from the [\*] otherwise applicable, and the applicable [\*]. If at any time after [\*] the Compound that [\*] Study [\*], as applicable, then GSK shall [\*].

**2.7.4** Proof of Concept Criteria. Upon the completion of any Proof of Concept Study, Dynavax shall promptly notify GSK in writing of such event and shall provide to the JSC a complete data package containing all analyses, results and raw data from the completion of the Proof of Concept Study for such Phase I Ready Compound, and any related correspondence and information received from or sent to any Regulatory Authority relating to such Phase I Ready Compound (the "PoC Study Report"). GSK shall have the right to exercise its Option to such Dynavax Program upon the completion of the Proof of Concept Study pursuant to Section 4.1 (whether or not such criteria have been satisfied). Unless otherwise agreed by the Parties, if requested by GSK, the JSC will schedule an ad hoc meeting not more than [\*] Calendar Days after receipt of any such PoC Study Report to review such PoC Study Report and confirm whether or not such Phase I Ready Compound satisfies the Proof of Concept Criteria. If the JSC [\*] decides that the Phase I Ready Compound did not satisfy the Proof of Concept Criteria, then, except as provided in Section 5.3, Dynavax will [\*] with respect to such Dynavax Program, and GSK may, [\*]. In the event that the Compound fails to satisfy the Proof of Concept Criteria after completion of the Proof of Concept Study, [\*] which completed the PoC Study, in such case the [\*] and all other [\*] for such GSK Development Program shall all be [\*] from the [\*] otherwise applicable,

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and the applicable [\*]. If at any time after Option exercise the Compound that completed the PoC Study [\*], as applicable, then GSK shall [\*].

- 2.8 [\*]. During the [\*], the JSC will review the progress of each Dynavax Program and [\*]. The JSC may, [\*] decide to [\*] Dynavax Program(s) [\*] Dynavax Program(s) that [\*] Dynavax Programs, [\*]. For clarity, if prior to the exercise by GSK of an Option with respect to a given Dynavax Program, the JSC is not in agreement, [\*]. All such decisions shall be based on [\*]. Notwithstanding the above, after GSK exercises an Option with respect to a Dynavax Program, GSK may, [\*], GSK shall be obligated to [\*]. For the purposes of determining whether there is [\*], the TLR 7/9 Program shall [\*] (for example, if a Compound in the [\*] is being progressed, then the [\*] may be rendered [\*], either prior to or after Option exercise by GSK).
- **2.9 Reports.** Dynavax shall provide written progress reports on the status of each Dynavax Program, including without limitation summaries of data associated with Dynavax's Research and Development activities and a timetable for completion of the respective Dynavax Program. Dynavax shall provide such written report to JSC members at least [\*] Business Days in advance of the applicable JSC meeting.
- **2.10 Material Transfer.** To facilitate the conduct of the Programs, either Party may provide to the other Party certain biological materials or chemical compounds, such as cell-based assays or specific Compounds, owned by or licensed to the supplying Party for use by the other Party in furtherance of the Development Plans (such materials or compounds provided hereunder are referred to, collectively, as "**Materials**"). Except as otherwise provided under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used only in furtherance of the Programs and solely under the control of the other Party (or its Affiliates), shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in Research or testing involving human subjects, unless expressly agreed. The Materials supplied under this Section 2.9 are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. For the avoidance of doubt, this Section 2.10 shall not apply to any materials and/or Compounds supplied to GSK by Dynavax in accordance with Section 4.3 pursuant to the exercise by GSK of its Option for a Dynavax Program.

## 2.11 Regulatory Matters; Compliance.

**2.11.1** *Compliance.* Dynavax shall conduct all pre-clinical activities and Clinical Trials under this Agreement in good scientific manner and in compliance in all material respects with applicable laws, rules and regulations and all other applicable requirements of cGMP, good laboratory practice and current good clinical practice.

**2.11.2** Data Integrity.

**(a)** Dynavax acknowledges the importance to GSK of ensuring that the Dynavax Programs are undertaken in accordance with the following good data management practices:

(i) data are being generated using sound scientific techniques and processes;

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(ii) data are being accurately and reasonably contemporaneously recorded in accordance with good scientific practices by Persons conducting Research hereunder;

- (iii) data are being analyzed appropriately without bias in accordance with good scientific practices; and
- (iv) data and results are being stored securely and can be easily retrieved.
- **(b)** Dynavax agrees that it shall use Commercially Reasonable Efforts to carry out the Dynavax Programs so as to collect and record any data generated therefrom in a manner consistent with the above requirements as set forth in subsection (a) above.
- **2.11.3** *Ownership.* [\*] all regulatory filings for Compounds [\*]. Upon [\*] with respect to a Dynavax Program, Dynavax shall [\*] as soon as reasonably practicable of all regulatory filings for the resulting GSK Development Compounds (including Back-up Compounds), including all relevant INDs, and provide GSK with copies of such INDs and other regulatory filings and all pre-clinical and clinical data and results (including pharmacology, toxicology, formulation, and stability studies). Thereafter, [\*] and maintain all regulatory filings and Regulatory Approvals for GSK Development Compounds.
- **2.11.4** *Adverse Event Reporting*. Beginning on the Effective Date and continuing until such time, if any, that GSK exercises its Option with respect to a Dynavax Program, Dynavax shall be responsible for reporting all adverse drug reaction experiences related to Compounds in such Dynavax Program in connection with the activities of Dynavax under this Agreement to the appropriate Regulatory Authorities in the countries in the Territory in which such Compounds are being Developed, in accordance with the appropriate laws and regulations of the relevant countries and Regulatory Authorities. Dynavax shall provide GSK notice of such event within five (5) days and provide copies of all reports to GSK as soon as possible, including using Commercially Reasonable Efforts to provide such copies. Through the JSC, GSK shall have the right to review from time to time Dynavax's pharmacovigilance policies and procedures. GSK and Dynavax agree to cooperate and use good faith efforts to ensure that Dynavax's adverse event database is organized in a format that is compatible with GSK's adverse event databases.
- **2.12 Dynavax Program Costs.** Except as set forth in this Article 2, [\*] shall [\*] in connection with performing activities under a Dynavax Program.
- **2.13 Subcontracting.** Subject to the terms of this Agreement, each Party shall have the right to engage Affiliates or Third Party subcontractors to perform certain of its obligations under this Agreement. Any Affiliate or subcontractor to be engaged by a Party to perform a Party's obligations set forth in the Agreement shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. Notwithstanding the preceding, any Party engaging an Affiliate or subcontractor hereunder shall remain principally responsible and obligated for such activities. In addition, each Party engaging a subcontractor with respect to its obligations under a Dynavax Program shall in all cases retain or obtain exclusive Control of any and all intellectual property created by or used with the relevant Party's permission by such subcontractor directly related to such subcontracted activity under the Dynavax Program. The Party engaging a subcontractor under a Dynavax Program shall be solely responsible for all costs associated with obtaining such exclusive Control and rights to such intellectual property. For example and not

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by limitation, Dynavax shall ensure that it retains or obtains exclusive Control of any intellectual property created by or used with the relevant Party's permission by any academic or any contract research, manufacturing or development organization appointed by Dynavax to fulfill any of its obligations under this Agreement. However, it is understood that, in some cases, it may not be commercially reasonable for such Party [\*]. To the extent that such [\*] from any such subcontractor under a Dynavax Program, prior to entering into such arrangement with such subcontractor, such Party shall bring such matter to the JSC for the prior approval of the JSC to enter into such arrangement and for approval by the JSC of the licensing terms and conditions with respect to such arrangement.

## **ARTICLE 3**

## MANAGEMENT OF THE COLLABORATION

**3.1 Joint Steering Committee.** Promptly and in any event within [\*] days after the Effective Date, the Parties shall establish a committee (the "**Joint Steering Committee**" or "**JSC**") as more fully described in this Section 3.1. The JSC shall have review, oversight and decision-making responsibilities for all Research and Development activities performed under this Agreement, as more specifically provided herein. Each Party agrees to keep the JSC informed of its progress and activities under the Programs.

**3.1.1** *Membership.* The JSC shall be comprised of three (3) representatives (or such other number of representatives as the Parties may agree) from each of GSK and Dynavax. Each Party shall provide the other with a list of its initial members of the JSC no later than thirty (30) days prior to the first scheduled meeting of the JSC, which shall be no later than ninety (90) days after the Effective Date. Each Party may replace any or all of its representatives on the JSC at any time upon written notice to the other Party in accordance with Section 13.7 of this Agreement. Each representative of a Party shall have relevant expertise (either individually or collectively) in pharmaceutical drug discovery and development. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend meetings of the JSC as non-voting participants, subject to the confidentiality obligations of Article 9. The Parties shall designate a chairperson (each, a "Chairperson") to oversee the operation of the JSC and prepare minutes as set forth in Section 3.1.3, each such Chairperson to serve a twelve (12) month term. The right to name the Chairperson shall alternate between the Parties, with [\*] designating the first such Chairperson.

**3.1.2** *Meetings.* During the Research Term, the JSC shall meet in person or otherwise at least once each Calendar Quarter, and more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties shall agree. Subject to Section 5.5, upon conclusion of the Research Term, the JSC shall meet, in person or otherwise, at least once every Calendar Year to provide Dynavax an update regarding GSK's efforts to Develop and commercialize Compounds and GSK Products in the GSK Development Programs, including without limitation, material changes in the clinical development plans for GSK Products, status of regulatory filings, anticipated indications, anticipated launch dates, manufacturing issues, and the like. Meetings of the JSC that are held in person shall alternate between the offices of the Parties, or such other place as the Parties may agree. The members of the JSC also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. Each Party will bear all expenses it incurs in regard to participating in all meetings of the JSC, including all travel and living expenses.

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- **3.1.3** *Minutes*. The Alliance Manager from the Party other than the Party of the Chairman, shall be responsible for preparing and circulating minutes of each meeting of the JSC, setting forth, *inter alia*, an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JSC and a list of any issues to be resolved by the Executive Officers pursuant to Section 3.1.4. Such minutes shall be effective only after approved by both Parties. With the sole exception of specific items of the meeting minutes to which the members cannot agree and that are escalated to the Executive Officers as provided in Section 3.1.4 below, definitive minutes of all JSC meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain. If at any time during the preparation and finalization of the JSC minutes, the Parties do not agree on any issue with respect to the minutes, such issue shall be resolved by the escalation process as provided in Section 3.1.4. The decision resulting from the escalation process shall be recorded by the Alliance Manager in amended finalized minutes for such meeting.
- **3.1.4** *Decisions.* Except as otherwise provided herein, with respect to a given Program, all decisions of the JSC prior to Option exercise by GSK shall be made by [\*], with each Party having [\*]. In the event that the JSC [\*] on a matter regarding a Dynavax Program within [\*] Calendar Days after it has met and attempted to reach such decision, then, except for matters expressly identified in this Agreement as not subject to escalation to the Executive Officers pursuant to this Section 3.1.4, either Party may, by written notice to the other, have such issue referred to [\*] from time to time [\*], for resolution. [\*], which shall in no case be more than [\*] after the matter was referred to [\*], the issue shall be finally resolved as follows:
  - (a) [\*] shall have final decision-making authority with respect to any disputes concerning [\*].
  - **(b)** If the dispute concerns whether [\*], the disputed issue shall be [\*].
  - (c) GSK shall have final decision-making authority with respect to any disputes concerning [\*].
- **3.1.5** *Responsibilities.* The JSC shall perform the following functions, subject to the final decision-making authority of the respective Parties as set forth in Section 3.1.4(a), (b) and (c), some or all of which may be addressed directly at any given meeting of the JSC:
- (a) review and comment on the Development Plan for each Dynavax Program and monitor progress of activities under such Development Plan;
- **(b)** oversee and guide the progress of each Dynavax Program in accordance with the applicable Pre-Candidate Selection Criteria, Phase I Ready Criteria, [\*] Criteria and Proof of Concept Criteria;

(c) [ \* ];

(d) prepare, review, modify, update and approve each Proof of Concept Study Design and [\*] Study Design;

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- **(e)** identify the Dynavax Programs to be conducted by Dynavax under this Agreement;
- (f) assess the Proof of Concept Criteria and, if applicable, the [\*] Criteria, for each Dynavax Program;
- (g) [\*] that a Compound has satisfied the Pre-Candidate Selection Criteria, Phase I Ready Criteria, Proof of Concept Criteria,

or [ \* ] Criteria;

- **(h)** [\*] all Dynavax Programs and decide whether to [\*] a Dynavax Program;
- (i) except as otherwise provided in Section 3.1.8 below, discuss and attempt to resolve any deadlock issues submitted to it by any Subcommittee (as defined in Section 3.1.7), in accordance with the procedures established in Section 3.1.4;
- (j) serve as an information transfer vehicle, from time to time, to facilitate the discussion of Development and commercialization of GSK Products under GSK Development Programs;
- (k) periodically review the Development and commercialization of any GSK Product and GSK Development Plan and [\*]; and
- (I) such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

For clarity, the JSC shall not have any authority beyond the specific matters set forth above in this Section 3.1.5, and in particular shall not have any power to amend or modify the terms or provisions of this Agreement. In addition, GSK (and not Dynavax or the JSC) shall have the sole right to make decisions with respect to (i) the exercise of an Option; or (ii) subject to Section 5.5 and GSK's diligence obligations in Section 5.1.3, the Research, Development, progression, manufacture, and commercialization of Compounds or Products in GSK Development Programs.

- **3.1.6** *Dynavax*'s *Right to Withdraw*. Dynavax will have the right to withdraw from participation on and thereby terminate any of its rights and obligations to participate in the JSC at any time after the [\*] anniversary of the Effective Date upon written notice to GSK. Upon withdrawal by Dynavax from participation in the JSC, GSK will have the sole decision-making authority with respect to any matters that would otherwise have been subject to Sections 3.1.4(a) or 3.1.4(b) and GSK shall have the right in such event, in its sole discretion, to immediately terminate all of Dynavax's Co-Development and Co-Promotion rights, whether previously exercised or not, under this Agreement.
- **3.1.7** *Subcommittee(s)*. From time to time, the JSC may establish subcommittees to oversee particular projects or activities, as it deems necessary or advisable (each, a "**Subcommittee**"). Each Subcommittee shall consist of such number of members as the JSC determines is appropriate from time to time. Such members shall be individuals with expertise and responsibilities in the areas of pre-clinical development,

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clinical development, patents, process sciences, manufacturing, regulatory affairs, product development and/or product commercialization, as applicable to the stage of development of the project or activity.

3.1.8 Joint Patent Subcommittee. Within two (2) months after the Effective Date, the JSC shall establish a Subcommittee (the "Joint Patent Subcommittee" or "JPS") to be responsible for the coordination of the Parties' efforts in accordance with Article 8 of this Agreement, including the review and filing of patent applications and assessments of inventorship of inventions created during the Research Term under the Dynavax Programs. The JPS shall be comprised of an equal number of representatives from each of GSK and Dynavax and shall meet on such dates and at such places and times agreed to by the Parties. All decisions of the JPS on matters for which it has responsibility shall be made by consensus, with each Party having collectively one (1) vote in all decisions. In the event that the JPS is unable to reach a consensus decision within fifteen (15) Calendar Days after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue submitted to the chief patent counsel of GSK and of Dynavax (together, the "Chief Patent Counsel"), or such other person holding a similar position designated by GSK or Dynavax from time to time, for resolution. The Chief Patent Counsel shall meet promptly to discuss the matter submitted and to determine a resolution. Prior to exercise of an Option for a Dynavax Program, if the Chief Patent Counsel [\*] shall be binding upon the Parties without further review, and (b) with respect to [\*] related to such Program, then the decision of the chief patent counsel of [\*] shall be binding upon the Parties without further review. Each Party will bear all expenses it incurs in regard to participating in all meetings of the JPS, including all travel and living expenses. After exercise of an Option hereunder for a Dynavax Program, if the Chief Patent Counsel are unable to determine a resolution in a timely manner with respect to any Patents related to such Program, [\*].

**3.2 Alliance Managers.** Promptly after the Effective Date, each Party shall appoint an individual (who may not be an existing member of the JSC) to act as alliance manager for such Party (each, an "**Alliance Manager**"). Each Alliance Manager shall thereafter be permitted to attend meetings of the JSC as a nonvoting observer, subject to the confidentiality provisions of Article 9. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder including, but not limited to, the exchange of Information described in Section 2.9. The Alliance Managers shall also be responsible for assisting the JSC in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement(s) chosen by Dynavax or GSK, in their sole discretion, from time to time, shall be promptly provided to the other Party in accordance with Section 13.7 of this Agreement.

## **ARTICLE 4**

## **GRANT OF RIGHTS**

## 4.1 Options.

**4.1.1** *Grant.* Dynavax hereby grants to GSK the exclusive option, exercisable on a Dynavax Program-by-Dynavax Program basis at GSK's sole discretion, to obtain the exclusive license set forth in Section 4.2.1 (each, an "**Option**"), subject to the terms and conditions described in Sections 4.1.2 - 4.1.6 below. GSK shall be limited to exercising one Option per Dynavax Program, and on exercise of an Option and

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payment of the applicable Option exercise fee, GSK shall have rights to such Dynavax Program consisting of all Compounds under a given Dynavax Program. For the purposes of this Section 4.1, the [\*] and the [\*] shall be considered distinct Dynavax Programs, each subject to a separate Option.

**4.1.2** [\*] *Period.* For the two (2) Dynavax Programs other than [\*], the Parties will determine whether GSK may exercise the Option [\*] after a Phase I Ready Compound has completed the [\*] Proof of Concept Study, as applicable, as follows. Within [\*] after the JSC determines that a Compound has reached the Phase I Ready stage pursuant to Section 2.7.2(a), the Parties shall [\*] or Dynavax shall [\*], as applicable. If the Parties do not agree within such [\*] period, or if the Parties do agree that [\*], as applicable, then Dynavax shall continue to progress the Dynavax Program, and the Option for such Dynavax Program may be exercised only following completion of [\*] the Proof of Concept Study, as applicable; *provided*, however, that if in GSK's reasonable judgment as specified in a reasonably detailed written notice to Dynavax delivered within [\*] after attainment of the Phase I Ready stage, Dynavax does not [\*], as applicable, then GSK [\*]. For clarity, GSK may exercise the Option with respect to the TLR 7/9 Program under any of the following circumstances, at the sole discretion of GSK, but in any event [\*]: (i) after completion of the [\*] or Proof of Concept Study, as determined pursuant to Section 2.6.3, or (ii) pursuant to Section 4.1.3(b) or 4.1.3(c).

#### 4.1.3 Exercise.

(a) The "Option Period Start" with respect to a Dynavax Program will commence upon the receipt by GSK of written notice from Dynavax of the complete PoC Study Report, complete [\*] Study Report, or [\*], as the case may be, as well as access to GSK to the Dynavax data room containing the complete set of material or relevant clinical and preclinical information related to the applicable Dynavax Program. GSK shall decide whether or not to exercise the Option and may exercise the Option with respect to a Dynavax Program by written notice to Dynavax at any time within [\*] after the Option Period Start, unless extended pursuant to Section 4.1.5 or otherwise extended by the mutual written agreement of the Parties. Upon GSK's exercise of an Option and receipt by Dynavax of the applicable Option exercise fee set forth in Section 6.2.1(a) or 6.2.2(a) pursuant to the procedure set forth in Section 6.7, the Dynavax Program will become a GSK Development Program. Subject to Section 5.3.2, any Option exercise shall be irrevocable. GSK shall have the right, at any time after exercising the Option with respect to a Dynavax Program and at its sole discretion, to [\*] from the same Dynavax Program.

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| (b) In addition, in the event that either (i) a [ * ], or (ii) a [ * ] occurs (as defined below), GSK shall have the right to exercise                         |
|--|
| its Options to any and all Dynavax Programs, and to terminate Dynavax's [*] rights to participate in the JSC and related Subcommittees, at GSK's sole          |
| discretion, by providing written notice to Dynavax within [*] of (A) the event described in (i) above; or (B) the event described in (ii) above, provided that |
| within [*] Business Days after Dynavax notifies GSK pursuant to Section 10.2.9, Dynavax shall provide to GSK a written plan for [*] and the Parties shall      |
| meet to discuss such plan, and if such plan is not reasonably acceptable to GSK (as reasonably detailed in written notice to Dynavax) then a [*] shall have    |
| occurred. Upon the exercise by GSK of its Option to a Dynavax Program pursuant to this Section 4.1.3(b), the Option exercise fee and the applicable            |
| milestone payments and royalty payments due under Article 6 shall all be [*] as follows on a Program-by-Program basis for each Program with respect to         |
| which GSK exercises its Option:  |
| -  |

(1) if Option exercise occurs for a Dynavax Program with a lead Compound (other than the [\*]) that has not yet satisfied the Pre-Candidate Selection Criteria, then the Option exercise fee and the milestone and royalty payments shall be [\*];

(2) if Option exercise occurs for a Dynavax Program with a lead Compound that has satisfied the Pre-Candidate Selection Criteria but is prior to the Phase I Ready stage, then the Option exercise fee and the milestone payments and the royalty payments either (i) shall be [\*], for a Program other than [\*], or (ii) shall be [\*].

(3) if Option exercise occurs for a Dynavax Program with a lead Compound at the Phase I Ready stage, but prior to initiation of a Phase 2 Clinical Trial, then the Option exercise fee and the milestone payments and royalty payments shall all be [\*] from the payments that would have been payable under Article 6 had GSK exercised its Option after completion of the Proof of Concept Study;

(4) if Option exercise occurs for a Dynavax Program after the initiation of a Phase 2 Clinical Trial for such Program, then the Option exercise fee and the milestone payments and royalty payments shall be [\*] that would have been payable under Article 6 had GSK exercised its Option after the Proof of Concept Study; and

(5) if Option exercise occurs for a Dynavax Program pursuant to Section 4.1.3(b)(ii) wherein Dynavax has [\*] (i) within [\*] of the Effective Date of this Agreement, then, [\*] above of this Section 4.1.3(b), in the total amount of [\*], and, if such Option exercise occurs (ii) more than [\*] after the Effective Date but prior to [\*] after the Effective Date of this Agreement, then, [\*] above of this Section 4.1.3(b), in the total amount of [\*].

The respective obligations of the Parties with respect to exclusivity under Article 7 shall remain unchanged.

(c) In the event that a [\*], then within [\*] after the [\*], and quarterly thereafter, the Parties and the acquiror shall meet to discuss, in good faith and in as much detail and specifics as is practicable at the time, [\*] under this Agreement. If at any time in the [\*] following the [\*], GSK has a reasonable, good faith basis to believe, based on the plans, documents, actions or inactions of Dynavax [\*] that Dynavax [\*] has not or will not, with respect to any Program, employ diligent efforts or human and material resources that are at least equivalent to the diligent efforts and human and material

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resources that were employed by Dynavax for the Program prior to (and without any allowance for) any delay, disruption or de-prioritization of such Program as a result of or in contemplation of such [\*], then GSK shall provide written notice to Dynavax [\*], such notice to allege the specific basis for GSK's view that the diligent efforts or human and material resources being applied or to be applied to the Program in question are or are expected to be less than those that were applied to the Program by Dynavax [\*]. Dynavax [\*] shall notify GSK whether or not it plans to cure such deficiency, and if it so elects to cure, shall have a [\*] to cure any such deficiencies in efforts or resources so alleged by GSK. In the event that Dynavax [\*] notifies GSK that it does not intend to cure such deficiencies or GSK reasonably believes that such deficiency has not been corrected or cured within such [\*], GSK shall have the right to exercise its Options to any and all Dynavax Programs, and to terminate Dynavax's [\*] rights to participate in the JSC and related Subcommittees, at GSK's sole discretion, by providing written notice to Dynavax within thirty (30) days after such [\*] or such notice from Dynavax [\*]. Upon the exercise by GSK of its Option to a Dynavax Program pursuant to this Section 4.1.3(c), the Option exercise fee and the applicable milestone payments and royalty payments due under Article 6 shall all be [\*] as set forth in Section 4.1.3(b)(1)-(5) as applicable, on a Program-by-Program basis for each Program with respect to which GSK exercises its Option.

**4.1.4** Expiration or Termination of Option. If GSK does not exercise the Option with respect to a particular Dynavax Program within the applicable [\*] or GSK elects not to exercise the Option, then, subject to Section 4.1.5, the Option shall terminate with respect to such Dynavax Program, which shall become a Dynavax Development Program, and Dynavax will thereafter have all rights, itself or with or through an Affiliate or Third Party, (a) to Develop and commercialize all Compounds within the Dynavax Program, subject to any applicable royalty payments set forth in Section 6.5, and (b) to use any data, regulatory filings and know-how generated or used in the course of the Dynavax Program, to the extent such [\*] that are included in the Dynavax Development Program.

**4.1.5** *HSR and Equivalent Foreign Laws.* If GSK reasonably determines in good faith prior to the expiration of the applicable period for exercise of an Option for a particular Dynavax Program (the "**Option Deadline Period**") that the exercise of such Option is required to be filed with the Federal Trade Commission (the "**FTC**") under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. §18a) ("**HSR**") or with equivalent foreign governmental authorities under any similar foreign law, GSK shall provide written notice of exercise of the Option to Dynavax prior to the end of the Option Deadline Period, which notice shall include GSK's binding commitment to complete the exercise of the Option, subject only to HSR or other governmental clearance by the FTC or other governmental authority, and the Option Deadline Period automatically shall be extended for [\*] (the "**Option Deadline Extension Period**"). If the exercise of the Option does not comply with the requirements of Section 4.1 and this Section 4.1.5, including, for example, because it includes other conditions to the completion of the exercise of the Option other than the grant of HSR or other governmental clearance, then the Parties shall negotiate in good faith to determine an appropriate way to proceed. If HSR or other governmental clearance is not granted within the Option Deadline Extension Period, or if GSK receives a "Second Request" from the FTC or similar request for additional information from a governmental authority in connection with such filing, the Option Deadline Extension Period shall be extended for an additional period of time (not to exceed an additional [\*]) to permit GSK to obtain FTC or other governmental clearance or to respond to the Second Request or provide additional information to the governmental authority. If GSK elects not to respond to the Second Request or to withdraw its request for HSR or other governmental clearance or HSR, the Option shall terminate, and Dynavax shall have the same rights as are set

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HSR or other governmental clearance has not been granted by the end of the extended Option Deadline Extension Period, Dynavax and GSK shall promptly meet to discuss in good faith whether an additional extension of the Option Deadline Extension Period is reasonable under the circumstances, and to discuss and consider in good faith, where appropriate, the [\*], with the objective of placing each Party[\*] if the Program in question had not been included in the Agreement from the beginning as of the Effective Date. Notwithstanding the foregoing, nothing in this paragraph or the Agreement shall require either Party to divest any assets or to take action (beyond cooperation with the other Party) to respond to any Second Request.

**4.1.6** *Tolling of Payment Obligations.* If the exercise by GSK of any Option under Section 4.1 requires the making of filings under HSR, or under any similar premerger notification provision in the European Union or any other jurisdiction, then all rights and obligations related to the exercise of such Option (including payment of any Option exercise fee or other milestone) shall be tolled until the applicable waiting period has expired or been terminated or until approval or clearance from the reviewing authority has been received, and each Party agrees to cooperate at the request of the Party which decides in its sole discretion to respond to any such request for information to expedite review of such transaction. In the event that HSR clearance is not reasonably achievable within [\*] days from notification, the Parties shall discuss in good faith potential alternatives, including, without limitation, termination of the relevant Program or the Agreement, as may be mutually agreed between the Parties in good faith, and, where appropriate, to discuss and consider in good faith the renegotiation of their financial and other obligations under the Agreement with respect to the affected Program.

### 4.2 License Grants.

**4.2.1** *License to GSK*. Subject to the terms and conditions of this Agreement and upon GSK's exercise of the relevant Option in accordance with Section 4.1 and Dynavax's receipt of the applicable Option exercise fee, Dynavax and its Affiliates shall be hereby deemed to have granted and hereby grant to GSK the exclusive right and license (even as to Dynavax and its Affiliates, except for the limited purpose of conducting Research and Development activities with respect to Back-up Compounds or formulations as expressly contemplated under Section 5.2) in the Territory, with the right to grant sublicenses, under all of Dynavax's and its Affiliates' right, title and interest in and to the Exclusively Licensed IP to make, have made, use, sell, offer for sale and import Compounds under such Dynavax Program as and into GSK Products in the Field during the Term.

**4.2.2** *No Grant of Rights to Third Parties.* Until such time as the Option Deadline Period, including any Option Deadline Extension Period (as may be extended), for an Option granted to GSK pursuant to Section 4.1 with respect to a given Dynavax Program has expired or terminated (including, for example, because [\*] terminated a Dynavax Program), Dynavax and its Affiliates shall not grant to any Third Party rights to any Exclusively Licensed IP that are inconsistent with or that would interfere with the grant of the licenses that may result from the exercise of such Option by GSK hereunder. For the avoidance of doubt, the Parties understand and agree that for so long as an Option is in effect, such Option shall be exclusive as to the Compounds that are the subject of the relevant Dynavax Program, and Dynavax and its Affiliates shall have no right to offer or negotiate with any Third Party with respect to the grant to such Third Party of any right or license, or with respect to any settlement, consent judgment or other disposition of any action or proceeding under Article 8, or with respect to any other encumbrance of any kind, in or to any of such Compounds or any Exclusively Licensed IP that would interfere with the grant of the licenses resulting from the exercise of such

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Option to GSK hereunder. The grant of the Options by Dynavax hereunder is irrevocable except as provided under Article 12. GSK acknowledges that certain of the Exclusively Licensed IP to the extent that it pertains to compounds which are not Compounds or Products hereunder is subject to the terms and conditions of the [\*] and that such grant of rights, so long as such grant is consistent with and does not interfere with the grant of exclusive licenses in the Field and in the Territory from the exercise of an affected Option hereunder, shall not be deemed a breach of this Agreement.

**4.3 Technology Transfer after Option Exercise.** As soon as reasonably practicable after GSK exercises its Option for a Dynavax Program pursuant to Section 4.1 [\*], Dynavax shall deliver to GSK, at no cost to GSK, all Information and material in its possession and Control relating to the Compounds in such GSK Development Program, including those documents and materials set out in Exhibit G, and any other such Information as may be in Dynavax's Control and in the possession of any subcontractors (including third party manufacturers) appointed by Dynavax under Section 2.13, in each case in a format to be agreed between the Parties but which is in an electronically editable format suitable for eCTD submission. Dynavax shall provide such technology transfer services as may be reasonably necessary to [\*] the Compound manufacturing processes at GSK's or GSK's Third Party manufacturer's site; provided that GSK shall be responsible for [\*] to provide those services reasonably necessary to [\*] of the Compound manufacturing processes by GSK, and [\*] from Dynavax therefor. [\*]. Dynavax shall use Commercially Reasonable Efforts with respect to those activities for which it is responsible to ensure orderly transition and uninterrupted Development of the GSK Development Program.

# 4.4 Third Party Licenses.

- **4.4.1** During the Term, [\*] (a) required for the exploitation of Dynavax's proprietary platform technology or any other technology used by Dynavax in conducting a Dynavax Program or Dynavax Development Program, (b) obtained by Dynavax prior to the Effective Date, or (c) to the extent related to the composition of matter or method of use of a Compound as contemplated under a Dynavax Program.
- **4.4.2** With respect to any Third Party license necessary for the manufacture, formulation or commercialization of a GSK Product in a GSK Development Program (other than any license described in Section 4.4.1), after GSK exercises the Option with respect to such GSK Development Program, [\*] obligation to pay any amounts for Third Party licenses as set forth above shall terminate immediately if GSK or Dynavax (in the case of an uncured material breach by GSK) [\*].

### **ARTICLE 5**

### POST-EXERCISE ACTIVITIES

### 5.1 GSK Development and Commercialization.

**5.1.1** Following exercise of an Option with respect to a Dynavax Program, subject to Sections 5.2 and 5.5, GSK, either itself and/or by and through its Affiliates, Sublicensees or contractors, shall be responsible for all Research, Development, regulatory, manufacturing, marketing, advertising, promotional, launch and sales activities in connection with GSK Products containing Compounds from such Program. Except as set forth in Section [\*].

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**5.1.2** Subject to Section 5.5.1(c), GSK shall have sole decision-making authority with respect to the Research, Development, progression, regulatory activities, manufacturing and commercialization of any Compound within a GSK Development Program, without submitting such matter to the JSC or Senior Executive Officers. In the event that the [\*] for resolution. [\*] determine a resolution. [\*] in a timely manner, which shall in no case be [\*].

### **5.1.3** *GSK* Diligence.

(a) Following GSK's exercise of an Option with respect to a Dynavax Program, GSK shall use its Commercially Reasonable Efforts to Develop and commercialize [\*] in such GSK Development Program in [\*], subject to the provisions of Section 2.8. [\*] provided, however, that the Parties acknowledge and agree that, for the purposes solely of this Section 5.1.3(a), [\*], it is appropriate for [\*]. In the event that, as a result of any such [\*] Country, such right of Dynavax shall be exercised in a manner [\*] (collectively, the "Coordination Conditions"); provided that if the Coordination Conditions apply, if such Product is commercialized by Dynavax or any Affiliate or sublicensee thereof in such country [\*], and GSK [\*], then Dynavax or any Affiliate or licensee thereof shall, to the extent permitted under applicable law, [\*], as the case may be, or shall [\*] under this Section 5.1.3 in [\*]. For clarity, and without limiting any other provision of this Agreement, any dispute regarding the application or enforcement of this Section 5.1.3 shall be [\*].

**(b)** Notwithstanding the foregoing Section 5.1.3(a) and for the avoidance of doubt, Dynavax acknowledges and agrees that in the event it (or its Affiliates or sublicensee) commercializes a Product [\*] then, subject to applicable law, Dynavax shall not, and shall ensure that its Affiliates or any sublicensee shall not, [\*] unless mutually agreed in writing by the Parties, provided that [\*]. With respect to [\*]. If Dynavax (or its Affiliate or licensee) becomes aware that [\*], Dynavax shall, or shall cause its Affiliates and licensees to, to the extent permitted under applicable law, [\*].

# 5.2 Dynavax Post-Exercise Activities.

**5.2.1** *Back-up Compounds.* If, upon exercise of the Option with respect to a Dynavax Program, there are not [\*] Back-up Compounds in such Dynavax Program that [\*], then Dynavax shall continue, until [\*] after GSK exercises such Option, to Develop [\*] Back-up Compounds that [\*] for such Dynavax Program, at Dynavax's sole cost and responsibility. Such Back-up Compounds shall be subject to GSK's Option and included within the applicable GSK Development Program. For clarity, efforts undertaken pursuant to this Section 5.2.1 following expiration of the Research Term shall not be deemed to extend the Research Term, but shall be subject to Dynavax's obligation to use Commercially Reasonable Efforts.

**5.2.2** [\*] Development. If, after completion of a Proof of Concept Study for a Phase I Ready Compound from a Dynavax Program or GSK Development Program, Dynavax has not [\*] for such Compound for [\*] in the applicable Development Plan, then Dynavax shall continue to develop such [\*], at its sole cost and expense, notwithstanding GSK's exercise of the Option for the Dynavax Program; provided, however, that an [\*] of a Compound that is [\*] shall be considered a [\*], provided that it meets GSK's then current requirements for [\*].

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### 5.3 Dynavax Development Compounds.

**5.3.1** *Option Expiration; Dynavax Program Termination.* In the event that the Option Deadline Period, including any Option Deadline Extension Period (as may be extended), for an Option with respect to a particular Dynavax Program that is not [\*] expires without exercise, or in the event that the [\*] terminates a Dynavax Program, then such Dynavax Program shall become a Dynavax Development Program, and Dynavax shall have the exclusive right, at its sole discretion, to Research, Develop and commercialize all Compounds within such Dynavax Program as Dynavax Products in the Territory in the Field, alone or with any Third Party or through any Sublicensee, Affiliate or subcontractor. GSK will have no further obligations to make any milestone, royalty or other payments to Dynavax of any kind under Article 6 with respect to such Compounds or to make any milestone, royalty or other payments of any kind to Dynavax, its Affiliate or any Third Party on account of any Third Party licenses for any such Compounds, except for any [\*]. Dynavax shall have the right to use, in connection with such Development and commercialization, [\*] without limitation if such materials are [\*], but for any Information that is [\*], Dynavax may only use the Information [\*]. If Dynavax or its Affiliate or Sublicensee Develops and commercializes a Dynavax Product pursuant to such Dynavax Development Program, Dynavax shall pay to GSK the applicable royalty payments as set forth in Section 6.5 for such Dynavax Products.

**5.3.2** *GSK Development Termination.* After exercising an Option with respect to a particular Dynavax Program, GSK may, at its sole discretion and without any penalty or liability (other than the transfer of any data, regulatory filings and other Information and grant of rights contemplated under this Section 5.3.2), terminate its Development or commercialization of all the Compounds or GSK Products within such Program upon written notice to Dynavax. In such event, provided that such Program is [\*]: (a) all licenses in and to the Exclusively Licensed IP for such Compounds granted to GSK by Dynavax shall immediately terminate, (b) Dynavax shall have the right to continue Development and commercialization of such Compounds under a Dynavax Development Program, (c) the obligations of Dynavax and rights of GSK under [\*] with respect to such Program will terminate, and (d) GSK (i) hereby grants, conditional upon the occurrence of such termination, an [\*] to such Compounds and [\*] as of the time of such termination, to further Develop and commercialize such Compounds as Dynavax Products in the Territory in the Field, (ii) shall transfer to Dynavax, [\*] and as soon as reasonably practicable after such termination, (a) all material Information [\*] to such Compounds [\*], and (b) all [\*], (iii) shall reasonably cooperate with Dynavax [\*]. In the event of such termination, Dynavax shall pay to GSK the applicable royalty payments as set forth in Section 6.6 for Dynavax Products containing any such Compounds.

**5.4 Safety Data Exchange.** The Parties shall negotiate in good faith a safety data exchange agreement with respect to GSK Products within [\*] days of GSK's exercise of an Option. The safety data exchange agreement shall facilitate management of safety for all GSK Products covered under such agreement in accordance with standards that are no less stringent than in the ICH guidelines, such that the Parties would be able to comply with all regulatory and legal requirements regarding the management of safety data, by providing for the exchange of relevant information in appropriate format within applicable timeframes.

**5.5 Co-Development and Co-Promotion by Dynavax**. GSK hereby grants Dynavax an option to co-develop one (1) GSK Product and a related right to co-promote in the U.S. the GSK Product that Dynavax has elected to co-develop, as set forth in this Section 5.5.

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### **5.5.1** *Co-Development Option.*

(a) *Generally*. Within [\*] days following GSK's exercise of an Option with respect to a Dynavax Program, GSK shall provide to Dynavax [\*], and shall have the option (the "Co-Development Option"), exercisable by written notice to GSK within [\*] after receipt of the [\*], to co-Develop such GSK Product. If Dynavax elects to co-Develop a GSK Product, Dynavax shall be responsible for [\*] of the Co-Development Costs incurred by GSK from and after GSK's exercise of the Option for the applicable Dynavax Program, and the royalty rate applicable to such GSK Product shall be adjusted as set forth in Section 6.4.2(d).

(b) Co-Development Costs. Upon exercise of the Co-Development Option, Dynavax shall pay to GSK a one-time [\*] payment equal to [\*] of the total Co-Development Costs incurred by GSK up to such date for such GSK Product (but not for other Compounds or GSK Products in such GSK Development Program) from and after its exercise of the Option. For clarity, any payments made by GSK to Dynavax under Article 6 of this Agreement prior to Dynavax's exercise of the Co-Development Option shall not be considered Co-Development Costs. In addition, following exercise of the Co-Development Option, Dynavax shall be responsible for [\*] of the ongoing Co-Development Costs with respect to such GSK Product through and including approval of the NDA. The Parties shall make reconciling payments for such Co-Development Costs on a Calendar Quarter basis such that each Party bears its respective share (i.e., [\*]) of the Co-Development Costs incurred during the applicable Calendar Quarter. In the event that the actual Co-Development Costs are reasonably expected to exceed, as determined by the summation of actual costs to date and official GSK forecasts over the course of the remaining development plan, [\*] of the estimated costs for the Co-Development Costs as set forth in the GSK Development Plan and Budget, Dynavax shall have [\*].

(c) Co-Development Governance. After Dynavax exercises the Co-Development Option as to a particular GSK Product, the JSC or such Subcommittee designated by the JSC shall continue to oversee and make decisions with respect to the Development of the applicable GSK Product, and shall continue to meet on a Calendar Quarter basis or as mutually determined by the Parties. GSK shall continue to update the GSK Development Plan and Budget for such GSK Product, and shall submit such updated GSK Development Plan and Budget to the JSC for review and approval. In the event that the JSC cannot reach consensus on any decision with respect to the Development of such GSK Product, [\*]. For clarity, GSK shall not [\*].

(d) [\*] of Dynavax. In the event of a [\*] in which [\*], GSK shall have the right, at its sole discretion, to [\*].

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(a) On or before the date which is [\*] for a GSK Product for which Dynavax has exercised the Co-Development Option, GSK shall provide to Dynavax a written commercialization plan for such GSK Product (the "Product Marketing Plan"). Dynavax shall have the option, exercisable by written notice to GSK within [\*] after receipt of the Product Marketing Plan, to co-promote such GSK Product to [\*]. Promptly following Dynavax's exercise of such option, the Parties shall engage in good faith negotiations to prepare and execute a definitive co-promotion agreement describing the co-promotion activities of the Parties for such GSK Product in the United States (the "Co-Promotion Agreement"). The Co-Promotion Agreement will have [\*] after Dynavax exercises such option. In addition, where appropriate, the Parties shall enter into a supply and quality agreement.

**(b)** The Co-Promotion Agreement shall incorporate the terms and conditions set forth in this Section 5.5.2(b). Dynavax shall have the right to provide between [\*] and [\*] of the [\*]. All details contributed by Dynavax shall be conducted by Dynavax employees, and Dynavax may not use contract sales representatives to conduct such details. [\*] GSK shall be responsible for receiving and filling orders, booking of sales, controlling invoicing, collection of payments, returns, charge-backs and rebates on sales of the GSK Product in the United States, and shall have sole control over pricing strategies and distribution of the GSK Product in the United States. GSK shall have responsibility for preparing and producing all promotional materials for the GSK Product at its sole expense, provided, however, that the [\*]. GSK shall provide samples and promotional materials to Dynavax for distribution to physicians to whom it details the GSK Product. GSK shall develop and provide equivalent training programs and materials for the GSK Product to sales representatives of both Parties, which programs and materials shall be provided at cost to Dynavax for its sales representatives. Dynavax may terminate its co-promotion of the GSK Product at any time upon [\*] written notice to GSK, upon which termination Dynavax and GSK shall reasonably cooperate to transition to GSK Dynavax's co-promotion activities so as to minimize disruption to sales activity.

(c) [\*] Dynavax. In the event of a [\*] in which [\*], GSK shall have the right, at its sole discretion, to [\*].

### **ARTICLE 6**

### MILESTONES AND ROYALTIES; PAYMENTS

**6.1 Program Funding.** In partial consideration for the Options granted to GSK hereunder, GSK shall pay to Dynavax a non-refundable, non-creditable payment of Ten Million Dollars (\$10,000,000) [\*] after receipt of an invoice from Dynavax on or after the Effective Date.

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# **6.2 Development Milestones.**

**6.2.1** [ \* ].

(a) Subject to the terms and conditions set forth in Section 6.2.1(b) and 6.2.3, GSK shall make the non-refundable, non-creditable milestone payments to Dynavax that are set forth below [\*] after receipt of an invoice following occurrence of the corresponding milestone event with respect to Compounds and GSK Products resulting from the [\*].

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| <u>Event</u>                           | <u>Payment</u>                   |
|--|----------------------------------|
| [*]                                    |                                  |
| [*]                                    | [*]                              |
| First Dosing in Phase 1 Clinical Trial | \$6 million                      |
| [*]                                    | [*]                              |
| [*]*                                   | [*]                              |
| [*]                                    | [ * ]<br>(see paragraph b below) |
| [*]                                    | [ * ]<br>(see paragraph b below) |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [ <u>*</u> ]                     |
| [*]                                    | [*]                              |
| [*]                                    |                                  |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [*]                              |
| [*]                                    | [ <u>*</u> ]                     |
| [*]                                    | [*]                              |
| TOTAL                                  | [*]                              |

<sup>\*</sup> for the purposes of this Section 6.2.1(a) milestone table, the [ \* ] Study] would qualify for the milestone event for [ \* ].

**(b)** All of the milestones in Section 6.2.1(a), including the [\*] payment or the [\*] payment, are payable only once for the [\*] and only once for the [\*]. If, upon achievement of a milestone for the [\*], any previous milestone has not been paid for such Program, then each such previous milestone shall be payable along with the payment for the milestone then achieved (it being understood that the "[\*]" payment is

not payable for the [\*] and that "[\*]" payment is payable for either [\*] and not both). If, when GSK exercises its Option for the [\*], it has not exercised its Option for the [\*], then the payment for the "[\*]" shall be increased to [\*] for the [\*], or, if the Option is exercised at [\*], the payment for the "[\*]" shall be increased to [\*] for the [\*] is terminated and such Compound is replaced by a Back-up Compound or other Compound, then milestone payments will be paid for such Back-up Compound or other Compound only if the corresponding milestone payment was not already made for the lead Compound. For clarity, the milestones listed for the [\*] may be achieved by [\*] that achieves the milestones for the [\*], but not for any additional [\*]. If the [\*] Option is exercised, the difference between the [\*] Payment and the [\*] Payment will become payable as a further milestone upon [\*] for such Compound, as determined by GSK, or upon the occurrence of [\*].

**6.2.2** [ \* ].

(a) Subject to the terms and conditions set forth in Sections 6.2.2(b) and 6.2.3, GSK shall make the non-refundable, non-creditable milestone payments to Dynavax that are set forth below within [\*] after receipt of an invoice following the occurrence of the corresponding milestone event with respect to Compounds and GSK Products resulting from the Dynavax Programs [\*].

| <u>Event</u> | <u>Payment</u> |
|--------------|----------------|
| [*]          | [*]            |
| [*]          | [*]            |

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|              | Payment if Option Exercised | <u>Payment if Option Exercised after Proof of Concept Study (or if exercised after [ * ]</u> |  |
|--------------|-----------------------------|--|--|
| <b>Event</b> | <u>at [ * ]</u>             | <u>Study)</u>  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          |                             |  |  |
| [*]          | [*]                         | [*]  |  |
| [*]*         | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | <u>[*]</u>                  | [ <u>*</u> ]   |  |
| [*]          | [*]                         | [*]  |  |
| [*]          |                             |  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [*]                         | [*]  |  |
| [*]          | [ <u>*</u> ]                | [ <u>*</u> ]   |  |
| [*]          | [*]                         | [*]  |  |
| TOTAL        | [*]                         | [*]  |  |

<sup>\*</sup>for the purposes of this Section 6.2.2(a) milestone table, [\*] Study] would qualify for the milestone event for [\*].

**<sup>(</sup>b)** The milestones in Sections 6.2.2(a) are payable only once for each Dynavax Program [\*], provided that in each row, either the amount for exercise of Option [\*] or the amount for exercise of Option after Proof of Concept Study (or, if applicable, after [\*] Study, as shown in parentheses above) will be payable for each Program depending upon which Option is exercised by GSK, but not for both in a given Program. If, upon achievement of a milestone for a Dynavax Program, any previous milestone has not been paid for such Program, then each such previous milestone (for the applicable Option exercise time only) shall be payable along with the payment for the milestone then achieved. For clarity, the milestone event "[\*]" will be payable only if GSK does not exercise its Option at the [\*]. For clarity, the milestones listed for the [\*] may be achieved by either the same or a different Product that achieves the milestones for the [\*], but not for any [\*]. If the [\*] Option is exercised, the difference between the [\*] Payment and the [\*] Payment will

become payable as a further milestone upon [\*] for such Compound, as determined by GSK, or upon the occurrence of the [\*].

**6.2.3** *Credit.* GSK may offset up to [\*] in the aggregate of any amounts paid to Dynavax under Section 2.6.4 or 2.6.6 against the milestone payments in Sections 6.2.1 and 6.2.2, provided that such offset may reduce each milestone payment thereunder by no more than [\*], up to a cumulative total of [\*].

### 6.2.4 Milestone Event Definitions.

- **(a)** The phrase "[\*]" as used in this Article 6 and elsewhere in this Agreement means [\*].
- **(b)** The phrase "[\*]" as used in this Article 6 means [\*]. In the event that GSK or its Affiliate or Sublicensee [\*]. The phrase "[\*]" as used in this Article 6 means [\*]. In the event that GSK or its Affiliate or Sublicensee [\*].
  - **(c)** The phrase "[\*]" as used in this Article 6 means [\*].
- **6.3 Commercialization Milestones.** GSK shall pay to Dynavax, on a GSK Development Program-by-GSK Development Program basis, each of the one-time (per GSK Development Program), non-refundable, non-creditable milestone payments indicated below no later than [\*] after receipt of an invoice when the aggregate Annual Net Sales of all GSK Products in a GSK Development Program in the Territory (for all indications and without regard to formulation) first reaches the corresponding dollar values.

| Aggregate Annual Net Sales (Worldwide) | <u>Payment</u> |
|--|----------------|
| [*]                                    | [*]            |
| [*]                                    | [*]            |

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## 6.4 Royalties.

**6.4.1** Patent Royalty. GSK shall pay to Dynavax incremental royalties on Annual Net Sales of GSK Products, on a country-by-country and GSK Product-by-GSK Product basis, in those countries of the Territory in which [\*] of such GSK Product is covered by a Valid Claim of a Patent within the Exclusively Licensed IP as of the First Commercial Sale of such GSK Product, or the GSK Product [\*] (the "Patent Royalty") at royalty rates as set forth in the table below, except that [\*] GSK exercised the Option with respect to the applicable Dynavax Program, the royalty rates shall be [\*] from the rates that are otherwise applicable below. The penultimate sentence of Section 6.4.2(a) shall apply upon the issuance of a Valid Claim of a Patent within the Exclusively Licensed IP that covers [\*] of a GSK Product, subject to the terms of this Section 6.4. The applicable royalty rates for a particular GSK Product shall depend on whether the GSK Product contains a Compound (a) [\*], (b) [\*] and GSK exercised the Option [\*], or (c) from another Program and GSK exercised the Option after the [\*].

|   | Royalty Rate |                     |                    |
|---|--------------|---------------------|--------------------|
| Annual Net Sales                                  | [*]          | [ * ] <u>-[ *</u> ] | [ * ] <u>[ *</u> ] |
| First [ * ]                                       | [*]          | [*]                 | [*]                |
| Portion above [ * ] and up to and including [ * ] | [*]          | [*]                 | [*]                |
| Portion above [*]                                 | [*]          | [*]                 | [*]                |

The royalty rates above are incremental rates that apply only for the respective increment of worldwide Annual Net Sales described in the Annual Net Sales column and, thus, once a total Annual Net Sales figure is achieved for the year, the royalties owed on any lower tier portion of Annual Net Sales are not adjusted up to the higher tier rate. The Patent Royalty as provided in this Section 6.4.1. shall be adjusted as provided in Section 6.4.2.

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## 6.4.2 Royalty Adjustments.

(a) Know-How Royalty. If, on a country-by-country and GSK Product-by-GSK Product basis, there is no Valid Claim of a Patent in the Exclusively Licensed IP that covers [\*] of the GSK Product at the time of First Commercial Sale (or such Valid Claim exists at the time of First Commercial Sale and subsequently expires) and no applicable data exclusivity exists under statute, regulation or other governmental action at the time of sale, but such [\*] is covered by either (i) a pending claim of a patent application within the Exclusively Licensed IP or (ii) Information within the Exclusively Licensed IP that has been maintained as a trade secret as evidenced by Dynavax's, or for jointly owned Information, both Dynavax's and GSK's, written records up until the time of such Net Sales of such GSK Product, then GSK shall pay to Dynavax a know-how royalty on Net Sales of such GSK Product in such country at royalty rates equal to [\*] of the rates set forth in the table in Section 6.4.1 above (the "Know-How Royalty"), subject to the remainder of this Section 6.4.2 and Section 6.4.3, and subject to a further reduction (in addition to the reductions set forth in the remainder of Section 6.4.2 and 6.4.3) of [\*] from the Know-How Royalty rates that would otherwise be applicable if the only pending claim of a patent application within the Exclusively Licensed IP or the only Information within the Exclusively Licensed IP qualifying under this paragraph is [\*] with respect to the applicable Dynavax Program. If such pending claim subsequently issues, then the rates set forth in the table in Section 6.4.1 and as adjusted under Section 6.4.1 above shall thereafter apply, and GSK shall pay to Dynavax an amount equal to the amounts previously paid with respect to GSK Products covered by such claim under this Section 6.4.2(a). In no event shall a Know-How Royalty be payable for Net Sales of a GSK Product in a country during any period in which a Patent Royalty is payable for such GSK Product in such country.

**(b)** Royalty Reduction for Competition. If at any such time that a Third Party product that has been approved for sale by the relevant Regulatory Authority in reliance on the MAA or NDA or their equivalent of a GSK Product (a "Generic Product") enters the market in a given country, and such Generic Product accounts for more than [\*] of aggregate unit sales of GSK Products and Generic Product in the given country, as measured by IMS Health or its successor, the Patent Royalty or Know-How Royalty, as applicable as set forth in Section 6.4.1 or 6.4.2(a), respectively, shall be reduced by [\*] in such country.

(c) Third Party Licenses. GSK shall be entitled to a credit against the royalty payments due to Dynavax on Net Sales of a GSK Product in a particular country of an amount equal to [\*] of the [\*] that are paid by GSK or its Affiliates or Sublicensees to a Third Party with respect to such GSK Product in such country for any license obtained after the exercise of the Option with respect to such GSK Product that is necessary for the commercialization of such GSK Product, as and to the extent set forth in Section 4.4.2, such credit not to exceed [\*] of the royalty that would otherwise be due to Dynavax on Net Sales of such GSK Product, provided that GSK shall have the right to carry forward for application in future periods any uncredited amount.

(d) *Co-Development*. If Dynavax exercises its option to co-develop a GSK Product under Section 5.5, the royalty rate applicable to such GSK Product shall be increased by [\*] above the applicable royalty rate set forth under Section 6.4.1, as adjusted pursuant to this Section 6.4.2.

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- **6.4.3 Royalty Term.** GSK's obligation to pay a Patent Royalty with respect to a GSK Product shall commence upon the First Commercial Sale of such GSK Product in a particular country in the Territory and will expire on a country-by-country and GSK Product-by-GSK Product basis upon the [\*] of (a) the [\*] of the GSK Product, or (b) [\*] with respect to such GSK Product. GSK's obligation to pay a Know-How Royalty with respect to a GSK Product shall commence upon the First Commercial Sale of such GSK Product in a particular country in the Territory and will expire on a country-by-country and GSK Product-by-GSK Product basis [\*] after First Commercial Sale in such country.
- **6.5 Royalty Payments by Dynavax No Exercise of Option by GSK**. With respect to any Dynavax Program that becomes a Dynavax Development Program upon GSK's failure to exercise or termination of its Option with respect thereto, or upon the JSC's or GSK's termination of such Dynavax Program, if Dynavax elects to Develop and/or commercialize Dynavax Products from such Program, Dynavax shall pay to GSK a royalty on Net Sales of such Dynavax Products at the following rates:
  - (a) [\*] if [\*] before such Dynavax Program became a Dynavax Development Program; and
  - **(b)** [\*] if [\*] before such Dynavax Program became a Dynavax Development Program.

Dynavax's obligation to pay royalties under this Section 6.5 with respect to a Dynavax Product shall commence upon the First Commercial Sale of such Dynavax Product in a particular country in the Territory and will expire on a country-by-country and Dynavax Product-by-Dynavax Product basis at the [\*].

- **6.6 Royalty Payments by Dynavax Post-Option Termination by GSK**. With respect to any GSK Development Program that becomes a Dynavax Development Program upon GSK's termination of its rights with respect thereto following Option exercise, if Dynavax elects to Develop and/or commercialize Dynavax Products from such Program, Dynavax shall pay to GSK a royalty on Net Sales of such Dynavax Products at the following rates:
  - (a) [\*] if GSK terminated such GSK Development Program [\*] from such Program anywhere in the Territory; and
  - (b) [\*] if GSK terminated such GSK Development Program [\*] from such Program anywhere in the Territory.

Dynavax's obligation to pay royalties under this Section 6.6 with respect to a Dynavax Product shall commence upon the First Commercial Sale of such Dynavax Product in a particular country in the Territory and will expire on a country-by-country and Dynavax Product-by-Dynavax Product basis upon the [\*] Dynavax Product, or (ii) [\*] after the [\*] in such country.

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**6.7 Reports and Payment of Milestones**. GSK shall make all milestone payments within [\*] after receipt by GSK of an invoice from Dynavax with respect to the achievement of such milestone event after GSK has notified Dynavax of achievement of the milestone event in accordance with the terms of this Section 6.7. Upon exercise of an Option by GSK, GSK shall pay the applicable Option exercise fee within [\*] of receipt of an invoice from Dynavax after notice from GSK of Option exercise pursuant to Section 4.1.3. Dynavax shall notify GSK in writing promptly, but in no event later than [\*], after each achievement of the "[\*]" and, if GSK has not exercised the Option at the [\*], "[\*]" milestones set out in Section 6.2 (it being understood that if Dynavax is conducting a [\*] Study, the [\*] Study shall qualify as the milestone event for [\*]"). GSK shall notify Dynavax in writing promptly, but in no event later than [\*], after the achievement of (a) the earlier of (i) the [\*] or (ii) the [\*] or [\*], as applicable, for a Program for which GSK exercised the Option after a [\*] Study, (b) all other milestones in Section 6.2 and (c) each milestone event set forth in Section 6.3. Subject to Section 4.1.5, GSK shall pay all milestone payments due (other than for Option exercise) within [\*] after receipt of an invoice for such payment from Dynavax following the achievement of the corresponding milestone event.

**6.8 Reports; Royalty Payments.** Until the expiration of a Party's royalty obligations under this Article 6, such Party agrees to make written reports to the other Party within [\*] days after the end of each Calendar Quarter covering all sales of Products in the Territory by such Party and its Affiliates and Sublicensees for which invoices were sent during such Calendar Quarter, each such written report in reasonable detail as available to such Party stating for the period in question: (a) the total Net Sales for each Product and (b) a calculation of the royalty payment due on such Net Sales pursuant to Article 6. The information contained in each report under this Section 6.8 shall be considered Confidential Information of the Party providing the report. Concurrent with the delivery of each such report, the Party delivering such report shall make the royalty payment due the other Party under Article 6 for the Calendar Quarter covered by such report. In the case of transfers or sales of any Product between the royalty-paying Party and an Affiliate or Sublicensee of such Party, a royalty shall be payable only with respect to the sale of such Product to an independent Third Party and not an Affiliate or Sublicensee of the seller.

**6.9 Methods of Payments.** All payments due from one Party (the "**Payor**") to the other Party (the "**Payee**") under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the Payee.

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**6.10** Accounting. Payor agrees to keep full, clear and accurate records for a maximum period of [\*] after the relevant payment is owed pursuant to this Agreement, setting forth the sales and other disposition of Product sold or otherwise disposed of in sufficient detail to enable royalties and compensation payable to the Payee hereunder to be determined. Payor further agrees, upon not less than [\*] Calendar Days prior written notice, to permit the books and records relating to such [\*] to be examined by an independent accounting firm selected by Payee and reasonably acceptable to Payor for the purpose of verifying reports provided by Payor under Section 6.8. Such audit shall not be performed more frequently than [\*] and shall be conducted under appropriate confidentiality provisions, for the sole purpose of verifying the accuracy and completeness of all financial, accounting and numerical information and calculations provided under this Agreement. Such examination is to be made at the expense of Payee, except in the event that the results of the audit reveal an underpayment of royalties, milestones, or other payments to Payee under this Agreement of [\*] or more per annum over the period being audited, in which case reasonable audit fees for such examination shall be paid by Payor. When calculating Net Sales, the amount of such sales in foreign currencies shall be converted into Dollars using the standard methodologies employed by Payor for consolidation purposes. Payor shall provide reasonable documentation of the calculation and reconciliation of the conversion figures on a country-by-country basis as part of its report of Net Sales for the period covered under the report.

# 6.11 Taxes.

**6.11.1** Subject to Section 6.11.2, any tax paid or required to be withheld by GSK for the benefit of Dynavax on account of any royalties or other payments payable to Dynavax under this Agreement shall be deducted from the amount of royalties or other payments otherwise due. GSK shall secure and send to Dynavax proof of any such taxes withheld and paid by GSK for the benefit of Dynavax, and shall, at Dynavax's request, provide reasonable assistance to Dynavax in recovering such taxes. Pending receipt of formal certification from the UK Inland Revenue, GSK may pay royalty income and any other payments under this Agreement to Dynavax by deducting tax at a rate specified in the double tax treaty between the UK and US. Dynavax shall provide the appropriate documentation necessary for GSK not to withhold amounts under the applicable terms of the double tax agreement between the UK and US. Dynavax agrees to indemnify and hold harmless GSK against any loss, damage, expense or liability arising in any way from a breach of the foregoing or any breach of Section 10.2.7 with respect to any claim by a UK tax authority or other similar body alleging that GSK was not entitled to deduct withholding tax on such payments at source at the treaty rate.

**6.11.2** If GSK or any GSK Affiliate is or becomes liable to withhold any taxes from payments made to Dynavax under Section 6.11.1 as a result of any permitted assignment by GSK pursuant to Section 13.4, [\*]. Dynavax shall provide GSK with such reasonable evidence as GSK may reasonably request to determine whether the taxes are creditable against taxes payable by Dynavax.

**6.11.3** If Dynavax is required to withhold any taxes from payments made to GSK under Section 6.11.1, as a result of an assignment pursuant to Section 13.4, [\*]. GSK shall provide Dynavax with such reasonable evidence as Dynavax may reasonably request to determine whether the taxes are creditable against taxes payable by GSK.

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**6.12 Late Payments.** Any undisputed amount owed by Payor to Payee under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the rate of [\*] above the then-applicable prime commercial lending rate of Citibank, N.A., San Francisco, California, or, if lower, the highest rate permitted under applicable law.

# **ARTICLE 7**

# **EXCLUSIVITY**

- **7.1 Dynavax Exclusivity.** Except pursuant to this Agreement, on a Program-by Program basis during the [\*] thereafter, Dynavax and/or its Affiliates shall not, either alone or with or for any Third Party, Research, Develop or commercialize any compound in the Field that is [\*] as a Compound any TLRs or combinations thereof that are the subject of [\*]. For clarity, nothing in this Section 7.1 shall limit Dynavax's rights to Develop or commercialize on its own or with or for a Third Party Compounds and Dynavax Products within a Dynavax Development Program, if such Program results from termination or expiration of the Option Deadline Period, including any Option Deadline Extension Period (as may be extended), for an Option without exercise by GSK, the JSC's or GSK's decision to terminate a Dynavax Program, or the termination of a GSK Development Program.
- **7.2 GSK Exclusivity**. Except pursuant to this Agreement, on a Program-by-Program basis during the [\*] thereafter, GSK and/or its Affiliates shall not, either alone or with or for any Third Party, Research, Develop or commercialize any [\*] as a Compound, any TLRs or combinations thereof that are the subject of any [\*].
- **7.3 Clarification.** For clarity, if [\*] is the subject of a Dynavax Program, then the restrictions in Sections 7.1 and 7.2 shall not apply to a Party's Research, Development, or commercialization, whether alone or together with or for the benefit of a Third Party, of a [\*] that is the subject of such Dynavax Program, provided that [\*]. Notwithstanding the above, GSK shall have the right to in-license rights from a Third Party, or to conduct research, development or commercialization with respect to any [\*], provided that the [\*] is not itself the subject of a [\*] to develop [\*]. Upon GSK's in-license or commencement of research, development or commercialization of such a [\*], the restrictions set forth in Section 7.1 shall not apply to [\*]. In the event that the limitation on a TLR does not apply as set forth in the preceding sentence, Dynavax and/or its Affiliates shall nevertheless [\*] any Research, Development or commercialization activities, either on its own or together with or for the benefit of any Third Party, (i) with respect to a [\*], during the [\*], or (ii) with respect to a [\*] during the [\*], if such TLR is not then the subject of a Dynavax Program. If GSK [\*], Dynavax shall [\*]. If Dynavax has not, as may be permitted above in this Section 7.3, previously entered into an agreement with a Third Party regarding a TLR released from the limitations of Section 7.1 as set forth above, GSK may request pursuant to Sections 2.5 and 3.1.4(c) at any time during the respective [\*] periods that Dynavax initiate and conduct such activities exclusively with GSK as a Dynavax Program under this Agreement.
- **7.4 Dynavax Exclusivity Exceptions**. Notwithstanding the foregoing in Section 7.1, Dynavax will have the right to perform the following activities:

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**7.4.1** Continue to research, develop, manufacture and commercialize compounds which do not qualify under the definition of Compounds hereunder in accordance with [\*]. For the avoidance of doubt, nothing herein will impair or interfere with Dynavax's obligations under [\*]

**7.4.2** Continue to research, develop, manufacture and commercialize compounds which do not qualify under the definition of Compounds hereunder in accordance with [\*].

# **ARTICLE 8**

# OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

# 8.1 Ownership.

**8.1.1** *Dynavax Compound IP and GSK Development IP.* Dynavax shall retain all of its rights, title and interest in and to the Dynavax Compound IP, and GSK shall retain all of its rights, title and interest in and to the GSK Development IP, except to the extent that any rights or licenses are expressly granted by one Party to the other Party under this Agreement.

**8.1.2** Intellectual Property Arising During Research & Development Activities. GSK shall be the sole owner of any Patents and Information discovered, developed, invented or created solely by or on behalf of GSK personnel under this Agreement, and GSK shall retain all of its rights, title and interest thereto, except to the extent that any rights or licenses are expressly granted thereunder by GSK to Dynavax under this Agreement. Dynavax shall be the sole owner of any Patents or Information discovered, developed, invented or created solely by or on behalf of Dynavax personnel under this Agreement, and Dynavax shall retain all of its rights, title and interest thereto, except to the extent that any rights or licenses are expressly granted thereunder to GSK under this Agreement. Any Patents or Information that are discovered, developed, invented or created jointly by or on behalf of GSK and Dynavax under this Agreement shall be owned jointly by GSK and Dynavax, and all rights, title and interest thereto shall be jointly owned by the Parties, subject to any exclusive rights or licenses that are expressly granted to a Party under this Agreement. Except as expressly provided in this Agreement, neither Party shall have [\* ], by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

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### 8.2 Prosecution and Maintenance of Patents.

**8.2.1** *Dynavax Compound Patents.* As between the Parties, [\*] shall be responsible for the Prosecution and Maintenance of the Dynavax Compound Patents. Notwithstanding the foregoing, [\*] will use Commercially Reasonable Efforts to obtain a reasonable scope of patent protection for Compounds that satisfy the Pre-Candidate Selection Criteria covered by claims of Dynavax Compound Patents, using counsel of its own choice but reasonably acceptable to [\*] informed as to material developments with respect to the Prosecution and Maintenance of such Dynavax Compound Patents, including without limitation by providing copies of all substantive office actions or any other substantive documents that [\*] receives from any patent office, including without limitation notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions, and by providing [\*] the timely opportunity to have input into all substantive aspects of such Prosecution and Maintenance. [\*] in good faith, with respect to the Prosecution and Maintenance of any Dynavax Compound Patents shall be referred [\*] for resolution.

**8.2.2** *GSK Development Patents*. As between the Parties, GSK shall control the Prosecution and Maintenance of any Patents in the GSK Development IP ("GSK Development Patents"). Notwithstanding the foregoing, GSK shall use Commercially Reasonable Efforts to consult with Dynavax in connection with the Prosecution and Maintenance of the GSK Development Patents; provided, however, that GSK shall not be required to disclose any confidential information that is not specific to the Programs. Input shall be provided and consideration undertaken and concluded by the Parties in a timely manner so as not to jeopardize the pendency of the application under review or otherwise negatively affect or limit the rights of any Party hereto. Should the Parties fail to agree on any matter in this Section 8.2.2, GSK shall have the final say on such matter.

### **8.2.3** Collaboration Patents.

(a) [\*] shall be responsible for the Prosecution and Maintenance of the Collaboration Patents solely [\*]. Notwithstanding the foregoing, [\*] will use Commercially Reasonable Efforts to obtain a reasonable scope of patent protection for Compounds that satisfy the Pre-Candidate Selection Criteria covered by claims of such Collaboration Patents, using counsel of its own choice but reasonably acceptable to [\*] informed as to material developments with respect to the Prosecution and Maintenance of such Patents, including without limitation by providing copies of all substantive office actions or any other substantive documents that [\*] receives from any patent office, including without limitation notice of all interferences, reissues, reexaminations, oppositions or requests for patent term extensions, and by providing [\*] the timely opportunity to have input into all substantive aspects of such Prosecution and Maintenance. [\*], with respect to the Prosecution and Maintenance of any Such Patents. Any dispute regarding the Prosecution and Maintenance of any Collaboration Patents [\*].

**(b)** GSK shall be responsible for the Prosecution and Maintenance of the Collaboration Patents solely owned by GSK. Notwithstanding the foregoing, GSK shall use Commercially Reasonable Efforts to consult with Dynavax in connection with the Prosecution and Maintenance of such Collaboration Patents. Any dispute regarding the Prosecution and Maintenance of any Collaboration Patents owned solely by GSK shall be [\*].

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(c) GSK shall be responsible for the Prosecution and Maintenance of the Collaboration Patents jointly owned by GSK and Dynavax. GSK shall keep Dynavax informed as to material developments with respect to the Prosecution and Maintenance of such Patents, including without limitation by providing copies of all substantive office actions or any other substantive documents that GSK receives from any patent office, including without limitation notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions, and by providing Dynavax the timely opportunity to have input into all substantive aspects of such Prosecution and Maintenance. GSK shall consult with Dynavax and shall take into account any comments from Dynavax in good faith, with respect to the Prosecution and Maintenance of any such Patents. Any dispute regarding the Prosecution and Maintenance of such Collaboration Patents shall be [\*].

- **8.2.4** *Filing Decision or Prosecution Lapse.* If, during the Term, the Party responsible Prosecuting and Maintaining a Patent in the Dynavax Compound Patents or Collaboration Patents in any country decides not to file such Patent or intends to allow such Patent to lapse or become abandoned without having first filed a substitute, the prosecuting or maintaining Party shall, whenever practicable, notify the other Party of such decision or intention at least [\*] Calendar Days prior to the date upon which the subject matter of such Patent shall become unpatentable or such Patent shall lapse or become abandoned, and such other Party shall thereupon have the right, but not the obligation, to assume responsibility for the Prosecution and Maintenance thereof at its own expense with counsel of its own choice.
- **8.2.5** *Prosecution and Maintenance Following GSK's Exercise of an Option.* Notwithstanding the foregoing, following GSK's exercise of an Option, GSK will be solely responsible for the Prosecution and Maintenance of all Patents in the Dynavax Compound IP and Collaboration Patents that contain claims covering GSK Development Compounds and GSK Products. Notwithstanding the foregoing in this Section 8.2, following GSK's termination of a GSK Development Program, Dynavax will be solely responsible for the Prosecution and Maintenance of the Dynavax Compound Patents and the Collaboration Patents owned solely by Dynavax or jointly by Dynavax and GSK.

### 8.3 Patent Costs.

- **8.3.1** *Collaboration Patents.* [\*] shall be responsible for all Patent Costs associated with the Prosecution and Maintenance of Collaboration Patents owned solely by Dynavax. [\*] shall be responsible for all Patent Costs associated with the Prosecution and Maintenance of Collaboration Patents owned solely by GSK or owned jointly by GSK and Dynavax.
- **8.3.2** *Dynavax Compound IP and GSK Development IP.* Dynavax shall be responsible for all Patent Costs incurred by Dynavax prior to and after the Effective Date with respect to any Dynavax Compound IP. GSK shall be responsible for all Patent Costs incurred by GSK prior to and after the Effective Date with respect to GSK Development IP.
- **8.3.3** *Patent Costs Following GSK's Exercise of an Option.* Notwithstanding the foregoing, following GSK's exercise of an Option, [\*] will be responsible for all Patent Costs going forward that are associated with the Prosecution and Maintenance of all Patents in the Dynavax Compound IP and Collaboration Patents that contain claims covering GSK Development Compounds and GSK Products.

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## 8.4 Defense of Claims Brought by Third Parties.

**8.4.1** Compounds. If a Third Party asserts that a Patent or other right owned by it is infringed by the manufacture, use, sale or importation of any Compound in a Dynavax Program as to which GSK has not exercised its Option, or any Compound within a Dynavax Development Program, Dynavax shall have the primary right but not the obligation to defend against any such assertions at its cost and expense. In the event Dynavax elects to defend against any such Third Party claims, Dynavax shall have the sole right to direct the defense of any such Third Party claims and to elect to settle such claims, but only with the prior written consent of GSK for a proposed settlement, not to be unreasonably withheld. In the event that Dynavax elects not to defend against such Third Party claims within [\*] Calendar Days of learning of same, GSK shall have the right to the detend against such action and thereafter shall have the right to direct the defense of any such Third Party claim(s), including the right to settle such claims, but only with the prior written consent of Dynavax for a proposed settlement, not to be unreasonably withheld. In any event, the Parties shall reasonably assist one another and cooperate in any such litigation at the other's request without expense to the requesting Party. Each Party may at its own expense and with its own counsel join any defense brought by the other Party.

**8.4.2** *GSK Development Compounds.* If a Third Party asserts that a Patent or other right owned by it is infringed by the manufacture, use, sale or importation of any GSK Development Compound or GSK Product, GSK shall have the primary right but not the obligation to defend against any such assertions at its cost and expense. In the event GSK elects to defend against any such Third Party claims, GSK shall have the sole right to direct the defense of such Third Party claims and to elect to settle such claims. In the event that GSK elects not to defend against such Third Party claims within [\*] Calendar Days of learning of same, Dynavax shall have the right, but not the duty, to defend against such an action and thereafter shall have the sole right to direct the defense of any such Third Party claim(s), including the right to settle such claims. In any event, the Parties shall reasonably assist one another and cooperate in any such litigation at the other's request without expense to the requesting Party. Each Party may at its own expense and with its own counsel join any defense brought by the other Party.

## 8.5 Enforcement of Dynavax or GSK Intellectual Property Rights.

**8.5.1** *Duty to Notify of Infringement.* If any Party learns of an infringement, unauthorized use, misappropriation or threatened infringement or other such activity by a Third Party with respect to any Collaboration IP, Dynavax Compound IP, or GSK Development IP ("Competitive Infringement"), such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such Competitive Infringement.

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### **8.5.2** Prior to Exercise of Option.

(a) Prior to GSK's exercise of an Option, with respect to any Collaboration IP solely owned by Dynavax or any Dynavax Compound IP that is the subject of such Competitive Infringement, Dynavax shall have the first right to bring and control any such action. Unless subject to an agreement between Dynavax and a Third Party in existence as of the Effective Date that would preclude Dynavax from granting such right to GSK, if Dynavax fails to bring any such action or proceeding within a period of [\*] Calendar Days after first being notified of such Competitive Infringement, then GSK shall have the right, but not the obligation, to bring and control any such action by counsel of its own choice, and Dynavax shall have the right to be represented in any such action by counsel of its own choice at its own expense.

**(b)** Prior to GSK's exercise of an Option, except as provided in Section 8.5.2(a), the Party responsible for Prosecuting and Maintaining a Collaboration Patent shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect thereto by counsel of its own choice, and the other Party shall have the right, at its own expense, to be represented in that action by counsel of its own choice. If the Party having the primary right fails to bring any such action or proceeding within a period of [\*] Calendar Days after first being notified of such Competitive Infringement, then the other Party shall have the right, but not the obligation, to bring and control any such action by counsel of its own choice, and the Party not bringing the action shall have the right to be represented in any such action by counsel of its own choice at its own expense.

**8.5.3** *Following Exercise of Option.* Following GSK's exercise of an Option, and before GSK's termination of Development and commercialization, with respect to the Program containing Compounds that are the subject of any Competitive Infringement, GSK shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect thereto by counsel of its own choice, and Dynavax shall have the right, at its own expense, to be represented in that action by counsel of its own choice. If GSK fails to bring an action or proceeding within a period of [\*] Calendar Days after first being notified of such Competitive Infringement, Dynavax shall have the right to bring and control any such action by counsel of its own choice, and GSK shall have the right to be represented in any such action by counsel of its own choice at its own expense.

**8.5.4** *After GSK*'s *Termination of a Program.* After GSK's termination of Development and commercialization with respect to a Program containing Compounds that are the subject of any Competitive Infringement of a Collaboration Patent, Dynavax shall have the sole right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect thereto by counsel of its own choice.

**8.5.5** *Settlement.* Any settlement, consent judgment or other disposition of any action or proceeding under this Article 8 shall not (a) include the grant of any license, covenant or other rights to any Third Party that would limit or interfere with or reduce the scope of the subject matter included under the exclusive licenses to be granted or granted to GSK pursuant to the exercise of any of its Options to Programs under Section 4.2.1, or (b) limit or interfere with or reduce the scope of the subject matter claimed in any patent owned (solely or jointly) by the other Party.

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**8.5.6** Share of Recoveries. If one Party brings any such action or proceeding in accordance with this Section 8.5, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the Party bringing suit under this Section 8.5 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (i) the amount of such recovery actually received by the Party controlling such action shall first be applied to the out-of-pocket costs of such action; and then (ii) any remaining proceeds shall be allocated between the Parties such that the Party bringing suit under this Section 8.5 retains [\*] and other Party retains [\*] of such amount. Any such damages or other monetary awards as recovery shall be [\*] of Net Sales for the purpose of determining royalties due under Article 6 hereunder. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 8.5 may be entered into without the consent of the Party not bringing the suit; provided that such settlement, consent judgment or other disposition does not admit the invalidity or unenforceability of the relevant Patent in the Dynavax Compound Patents, GSK Development Patents, or Collaboration IP, and provided further, that any rights granted under the relevant Patent to continue the infringing activity in such settlement, consent judgment or other disposition shall be limited to those rights that the granting Party otherwise has the right to grant, and provided further, that any settlement, consent judgment or other disposition shall not include the grant of any license, covenant or other rights to any Third Party that would limit or interfere with or reduce the scope of the subject matter included under the exclusive licenses to be granted to GSK pursuant to the exercise of any of its Options to Programs under Section 4.2.1.

**8.5.7** 35 USC 271(e)(2) Infringement. Notwithstanding anything to the contrary in this Section 8.5, for infringement under 35 USC 271(e)(2) where GSK has exercised its Option and where GSK is the holder of the applicable NDA, and for so long as GSK maintains or retains its exclusive license under such Option, GSK shall have the sole right to initiate legal action to enforce all Collaboration IP, GSK Development IP and Dynavax Compound IP licensed to it against infringement or misappropriation by Third Parties or defend any declaratory judgment action relating thereto at its sole expense.

**8.5.8** *Regulatory Data Protection.* To the extent required by law or permitted by law, each Party will use Commercially Reasonable Efforts to promptly, accurately and completely list, with the applicable Regulatory Authorities during the Term, all applicable Patents for any Product that such Party intends to, or has begun to, commercialize and that have become the subject of a marketing application submitted to FDA, such listings to include all so called "Orange Book" listings required under the Hatch-Waxman Act and all so called "Patent Register" listings as required in Canada. Prior to such listings, the Parties will meet to evaluate and identify all applicable Patents. Notwithstanding the preceding sentence, the Party holding the NDA for the applicable Product will retain final decision-making authority as to the listing of all applicable Patents for such Product, regardless of which Party owns such Patent.

**8.6 Other Agreement(s).** GSK's rights under this Article 8 with respect to any Dynavax Compound Patents or Collaboration Patents shall be subject to the rights that one or more Third Parties may have, or the obligations that Dynavax may have, in each case to file, prosecute, maintain, and/or enforce such Patents under the agreement(s) listed in Schedule 8.6, but only to the extent that any of such rights or obligations with respect to any Third Party under any of the Agreements listed in Schedule 8.6 pertain solely to compounds that do not qualify under the definition of Compounds hereunder.

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### ARTICLE 9

### **CONFIDENTIALITY**

- **9.1 Confidentiality; Exceptions.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Information or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party (the "Disclosing Party") or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement, including but not limited to trade secrets, knowhow, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and Research and Development activities of any product or potential product or useful technology of the Disclosing Party and the pricing thereof (collectively, "Confidential Information"), except to the extent that it can be established by the Receiving Party that such Confidential Information:
- **9.1.1** was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;
  - **9.1.2** was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- **9.1.3** became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or
- **9.1.4** was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

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**9.2 Authorized Disclosure.** Except as expressly provided otherwise in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows: (i) under appropriate confidentiality provisions similar to those in this Agreement, in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement (including, without limitation, the rights to commercialize Products and to grant licenses and sublicenses hereunder); or (ii) to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, obtaining regulatory approval, conducting pre-clinical activities or clinical trials, marketing Products, or otherwise required by law; *provided*, *however*, that if a Receiving Party is required by law or regulation to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; or (iii) in communication with investors, consultants, advisors or others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement; or (iv) to the extent mutually agreed to in writing by the Parties; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives the Confidential Information pursuant to this Section 9.2 to treat such Confidential Information as required under this Article 9.

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9.3 Press Release; Disclosure of Agreement. On or promptly after the Effective Date, the Parties shall jointly issue a public announcement of the execution of this Agreement in the form attached hereto as Exhibit F. Neither Party shall be free to issue any press release or other public disclosure regarding the Agreement or the Parties' activities hereunder, or any results or data arising hereunder, except (a) with the other Party's prior written consent, or (b) for any disclosure that is reasonably necessary to comply with applicable national securities exchange listing requirements or laws, rules or regulations, with the other Party's consent not to be unreasonably withheld or delayed beyond a time reasonably in advance of the required disclosure deadline necessary to comply with applicable national securities exchange listing requirements or laws, rules or regulations. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any such press releases prior to the issuance thereof, and a Party may not unreasonably withhold consent to such releases. Except to the extent required by law or as otherwise permitted in accordance with this Section 9.3, neither Party shall make any public announcements concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld. Each Party agrees to provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter thereof as soon as reasonably practicable under the circumstances prior to its scheduled release. Except under extraordinary circumstances, when the following notice may not be possible but in which event the press release will still be provided to the other Party for comment before release, each Party shall provide the other with an advance copy of any such announcements at least [\*] prior to its scheduled release. Each Party shall have the right to expeditiously review and recommend changes to any such announcement and, except as otherwise required by laws, rules or regulations, the Party whose announcement has been reviewed shall remove any Confidential Information of the reviewing Party that the reviewing Party reasonably deems to be inappropriate for disclosure. The principles to be observed by Dynavax and GSK in any such permitted public disclosures with respect to this Agreement shall be: accuracy and completeness, the requirements of confidentiality under this Article 9, and the normal business practice in the pharmaceutical and biotechnology industries for disclosures by companies comparable to Dynavax and GSK. Notwithstanding the foregoing, to the extent information regarding this Agreement has already been publicly disclosed in the same context, either Party may subsequently disclose the same information to the public without the consent of the other Party. Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, to any actual or potential acquirers, merger partners, and professional advisors. Each Party shall give the other Party a reasonable opportunity to review all filings with the United States Securities and Exchange Commission describing the terms of this Agreement prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including without limitation the provisions of this Agreement for which confidential treatment should be sought.

**9.4 Termination of Prior Agreement**. This Agreement supersedes the Confidentiality Agreement between Dynavax and GSK dated [\*] (including any and all amendments thereto). All information exchanged between the Parties under that agreement shall be deemed Confidential Information hereunder and shall be subject to the terms of this Article 9.

**9.5 Remedies.** Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 9.

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9.6 Publications. Neither Party or its Affiliates shall publish or publicly disclose the results of any of the Research and/or Development activities conducted by either Party under this Agreement without the prior written consent of the other Party, except as expressly permitted in this Section 9.6 or otherwise in this Agreement. The Parties recognize that it may be useful or required to publish or publicly disclose the results of Research and Development work on Programs, and each Party (and its Affiliates and Sublicensees) shall be free to publish or publicly disclose such results, subject to the prior review by the other Party for patentability and protection of its Confidential Information as described in this Section 9.6. For Dynavax, the publication right conveyed by the preceding sentence shall apply solely to Compounds prior to the exercise of an Option by GSK to the relevant Dynavax Program, if approved by GSK, such approval not to be unreasonably withheld or delayed. The Party that desires to publish results hereunder shall provide to the other Party a copy of such proposed abstract, manuscript, or presentation no less than [\*] prior to its intended submission for publication. The reviewing Party shall respond in writing promptly and in no event later than [\*] after receipt of the proposed material, with one or more of the following: (i) comments on the proposed material, which the publishing Party must consider in good faith, (ii) a specific statement of concern, based upon the need to seek patent protection or to block publication if the reviewing Party determines that the proposed disclosure is intellectual property that should be maintained as a trade secret to protect a Compound or any Research and/or Development activities conducted under this Agreement, or (iii) an identification of the reviewing Party's Confidential Information that is contained in the material reviewed. In the event of concern over patent protection or whether maintaining a trade secret would be a priority, the publishing Party agrees not to submit such publication or to make such presentation that contains such information until the reviewing Party is given a reasonable period of time ([\*]) to seek patent protection for any material in such publication or presentation which it believes is patentable or to resolve any other issues or to abandon such proposed publication if the reviewing Party reasonably determines in good faith that maintaining such information as a trade secret is a commercially-reasonable priority. Any Confidential Information of such other Party shall be removed. Furthermore, with respect to any proposed abstracts, manuscripts or summaries of presentations by investigators or other Third Parties, such materials shall be subject to review under this Section 9.6 to the extent that GSK or Dynavax (as the case may be) has the right to do so. For clarity, (a) prior to the exercise of the relevant Option to a given Program by GSK, any proposed publication by Dynavax relating to a Dynavax Program or any Compounds shall be subject to review by GSK in accordance with the terms of this Section 9.6, but after the expiration of the relevant Option without exercise by GSK or after the termination of a Program which then reverts to Dynavax, Dynavax shall then be free to publish or publicly disclose any results that relate to any Compounds or Dynavax Products in such Dynavax Program or Dynavax Development Program without any review by GSK under this Section 9.6, unless such proposed disclosure or publication contains any GSK Development IP, in which case GSK shall have the right to review and approve such disclosure as stated under this Section 9.6 above, and (b) after the exercise by GSK of its Option to a Program, except as required by law or securities regulations, Dynavax shall not have the right to make any publication relating to such Dynavax Program or any Compounds or GSK Development Compounds or GSK Products without the prior written consent of GSK, and GSK shall have the right to make any such publication relating to such Dynavax Program or any Compounds or GSK Development Compounds or GSK Products without any review by Dynavax under this Section 9.6.

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9.7 Clinical Trial Register. Each of GSK and Dynavax shall have the right to publish summaries of results from any human clinical trials conducted by such Party under this Agreement on its clinical trials registry, without requiring the consent of the other Party, subject to the last sentence of this Section 9.7; provided, however, that GSK shall have no right, without the consent of Dynavax, to so publish data generated by Dynavax prior to GSK's exercise of its Option with respect to the relevant Compounds under the relevant Dynavax Program, and, after the exercise of its Option to such Dynavax Program, GSK shall have the right to so publish any previously existing and/or any subsequently arising data that is or may be generated by either Dynavax or GSK or by their respective Affiliates or Sublicensees with respect to the relevant Compound(s) without obtaining the consent of Dynavax, except with respect to any Compounds which are being pursued under a Dynavax Development Program after termination by GSK of such Compounds as GSK Development Compounds or after GSK declines to exercise its Option with respect to such Dynavax Program. In addition, after the exercise of its Option by GSK to a particular Dynavax Program, Dynavax shall not have the right to publish any of such data, without the prior consent of GSK, pertaining to the relevant Compounds or the Dynavax Program, except with respect to any Compounds which are being pursued under a Dynavax Development Program after termination by GSK of such Compounds as GSK Development Compounds. The Parties shall discuss and reasonably cooperate in order to facilitate the process to be employed in order to ensure the publication of any such summaries of human clinical trials data and results as required on the clinical trial registry of each respective Party, and shall provide the other Party via submission to the Joint Patent Subcommittee established under Section 3.1.8, at least [\*

### **ARTICLE 10**

# REPRESENTATIONS AND WARRANTIES

- **10.1 Representations and Warranties of Both Parties**. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:
- **10.1.1** such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- **10.1.2** such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
- **10.1.3** this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;
- **10.1.4** the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party;

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- 10.1.5 no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws, rules or regulations currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements except as may be required to obtain HSR clearance; and
- 10.1.6 it has not employed (and, to the best of its knowledge without further duty of inquiry, has not used a contractor or consultant that has employed) any individual or entity debarred by the FDA (or subject to a similar sanction of EMEA), or, to the best of its knowledge without further duty of inquiry, any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMEA), in the conduct of any pre-clinical activities or clinical studies of Compounds.
- **10.2 Representations, Warranties and Covenants of Dynavax**. Dynavax hereby represents, warrants, and covenants to GSK, as of the Effective Date, and covenants to GSK during the Term (or the applicable portion thereof) as applicable for Sections 10.2.3 and 10.2.6-10.2.9, that:
  - **10.2.1** To its knowledge, Dynavax is the owner of, or has Control via a license to, the Dynavax Compound IP;
- **10.2.2** To its knowledge, Dynavax has the right to grant all rights and licenses it purports to grant to GSK with respect to the Dynavax Compound IP under this Agreement;
- 10.2.3 Except as set forth on Schedule 10.2 only with respect to compounds that do not qualify as Compounds as defined under this Agreement, Dynavax has not granted as of the Effective Date, and during the Term Dynavax shall not grant, any right or license, encumbrance, lien or other interest of any kind (other than general liens arising in the ordinary course of business which are not specific to any of the Dynavax Compound IP or to any Collaboration IP) to any Third Party relating to any of the Dynavax Compound IP or any of Dynavax's right, title or interest in any of the Collaboration IP that would conflict or interfere with or limit the scope of any of the rights or licenses granted or to be granted to GSK hereunder pursuant to the exercise of any Option to any Program;
- **10.2.4** Dynavax has not granted any liens or security interests on the Dynavax Compound IP or Collaboration IP under the Symphony Agreement or the AstraZeneca Agreement or any other collaboration or license agreement;
- 10.2.5 Dynavax has not withheld from GSK any material data or any material correspondence, including without limitation any correspondence to or from any Regulatory Authority, in existence as of the Effective Date with respect to the Dynavax Programs or Compounds that it is aware would have a material adverse effect upon GSK's scientific, commercial, safety and regulatory assessment of the liabilities of the collaboration between the Parties as contemplated under this Agreement;

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- 10.2.6 To its knowledge, Dynavax has disclosed or provided access to as of the Effective Date, and thereafter until the exercise or expiration of the Option with respect to a Dynavax Program shall disclose to GSK and exchange, all data and information and all correspondence to or from any Regulatory Authority then available, regardless of whether such data, correspondence and information would have a positive or negative impact on the potential commercial, scientific or strategic value or attractiveness of the Compounds, that is in Dynavax's reasonable business judgment material to a reasonable assessment by GSK of the scientific, commercial, safety, and regulatory liabilities of the Compounds to be considered by GSK in deciding whether or not to exercise its Option with respect to such Dynavax Program;
- **10.2.7** Dynavax is resident for tax purposes in the US and is entitled to relief from United Kingdom income tax under the terms of the double tax agreement between the UK and US and, during the Term, Dynavax shall notify GSK immediately in writing in the event that Dynavax ceases to be entitled to such relief and in such event, the withholding rights of GSK pursuant to Section 6.11.1 shall apply.
- **10.2.8** During the Term until the exercise or expiration of an Option with respect to a Dynavax Program, Dynavax will not knowingly use any compound in such Dynavax Program that, to its knowledge, is encumbered by any Third Party lien (other than general liens created in the ordinary course of business which are not specific to any of the Dynavax Compound IP or to any Collaboration IP) or restriction or any Third Party right or obligation that would conflict or interfere with any of the rights or licenses granted or to be granted to GSK hereunder pursuant to the exercise of such Option or by operation of the provisions of Article 12;
- 10.2.9 During the Term, Dynavax shall notify GSK in writing within ten (10) Calendar Days in the event that it has [\*], based upon then-current or reasonable [\*]; and
- **10.2.10** During the Term, Dynavax shall use its reasonable business judgment to [\*], to the extent necessary for GSK to make, have made, use, sell, offer for sale or import GSK Products.
  - 10.3 Mutual Covenants. Each Party hereby covenants to the other Party that:
- **10.3.1** All employees of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;
- 10.3.2 Such Party will not employ (or, to the best of its knowledge without further duty of inquiry, will not use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of EMEA) or, to the best of its knowledge without further duty of inquiry, any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMEA), in the conduct of its activities under any Program;

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10.3.3 Such Party shall (a) perform its activities pursuant to this Agreement in compliance with good laboratory and clinical practices and cGMP, in each case as applicable under the laws and regulations of the country and the state and local government wherein such activities are conducted; (b) with respect to the care, handling and use in Research and Development activities hereunder of any non-human animals by or on behalf of such Party, at all times comply (and shall ensure compliance by any of its subcontractors) with all applicable federal, state and local laws, regulations and ordinances, and also with the most current best practices for comparable-sized pharmaceutical or biotechnology companies for the proper care, handling and use of animals in pharmaceutical Research and Development activities, and at all times with the "3R Principles" (reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the Research techniques used), subject to the other Party's reasonable right of inspection; (c) promptly and in good faith undertake reasonable corrective steps and measures to remedy the situation to the extent that any significant deficiencies are identified as a result of such inspection; and (d) with respect to any biological samples obtained from humans, obtain the appropriate informed consents in advance for the use of all such human biological samples, and use such samples at all times within the scope of the relevant informed consents;

**10.3.4** Neither Party shall, during the Term, grant any right or license or encumbrance or lien of any kind (other than general liens created in the ordinary course of business which are not specific to any of the Dynavax Compound IP, the GSK Development IP, or to any Collaboration IP) to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict or interfere with any of the rights or licenses granted or to be granted to the other Party hereunder pursuant to the provisions of Article 4 or by operation of the provisions of Article 12; and

**10.3.5** Each Party will notify the other Party in writing promptly in the event that it has actual knowledge of the material breach of any covenant under Section 10.2 or this Section 10.3 or the material breach of any representation or warranty provided by either Party under Section 10.1 or by Dynavax under Section 10.2.

10.4 Disclaimer. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE OR THAT THEIR EXERCISE DOES NOT INFRINGE ANY PATENT RIGHTS OF THIRD PARTIES, AND EXPRESSLY DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to: (a) the success of any study or test commenced under this Agreement, (b) the safety or usefulness for any purpose of the technology or materials, including any Compounds, it provides or discovers under this Agreement; and/or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

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### **ARTICLE 11**

# INDEMNIFICATION; INSURANCE

- **11.1 Indemnification by GSK**. GSK shall indemnify, defend and hold harmless Dynavax and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses, including, but not limited to, the reasonable fees of attorneys and other professional Third Parties (collectively, "Losses"), arising out of or resulting from any and all Third Party suits, claims, actions, proceedings or demands ("Claims") based upon:
- **11.1.1** the negligence, recklessness or wrongful intentional acts or omissions of GSK and/or its Affiliates and its or their respective directors, officers, employees and agents, in connection with GSK's performance of its obligations or exercise of its rights under this Agreement;
- **11.1.2** any breach of any representation or warranty or express covenant made by GSK under Article 10 or any other provision under this Agreement;
- 11.1.3 the Development that is actually conducted by and/or on behalf of GSK (excluding any Development carried out by and/or on behalf of Dynavax hereunder), the handling and storage by and/or on behalf of GSK of any chemical agents or other compounds for the purpose of conducting Development by or on behalf of GSK, and the manufacture, marketing, commercialization and sale by GSK, its Affiliate or Sublicensee of any Compound or GSK Product; or
- 11.1.4 the alleged infringement or misappropriation of the intellectual property rights of any Third party or a claim or defense of unenforceability due to inequitable conduct brought before the United States Patent and Trademark Office or a United States District Court and any resulting antitrust claims arising therefrom, in each case, to the extent based upon or attributable to the Patents for which and to the extent GSK is responsible for the Prosecution and Maintenance under Article 8;

*except*, in each case above, to the extent such Claim arose out of or resulted from or is attributable to the negligence, recklessness or wrongful intentional acts or omissions of Dynavax and/or its Affiliates, or their respective directors, officers, employees or agents.

- **11.2 Indemnification by Dynavax**. Dynavax shall indemnify, defend and hold harmless GSK and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, arising out of or resulting from any and all Third Party Claims based upon:
- 11.2.1 the negligence, recklessness or wrongful intentional acts or omissions of Dynavax and/or its Affiliates and/or its or their respective directors, officers, employees and agents, in connection with Dynavax's performance of its obligations or exercise of its rights under this Agreement;
- **11.2.2** any breach of any representation or warranty or express covenant made by Dynavax under Article 10 or any other provision under this Agreement;

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11.2.3 the Research and/or Development actually conducted by or on behalf of Dynavax (excluding any Research and Development carried out by or on behalf of GSK or its Affiliate, Sublicensee or subcontractor, provided however that the Research and Development which is to be carried out by or on behalf of Dynavax hereunder shall not be considered or interpreted to be Research and Development carried out by or on behalf of GSK), the handling and storage by and/or on behalf of Dynavax of any chemical agents or other compounds for the purpose of conducting Research and/or Development by or on behalf of Dynavax, and the manufacture, marketing, commercialization and sale by Dynavax, its Affiliate or Sublicensee of any Compound or Dynavax Product; or

11.2.4 the alleged infringement or misappropriation of the intellectual property rights of any Third Party or a claim or defense of unenforceability due to inequitable conduct brought before the United States Patent and Trademark Office or a United States District Court and any resulting antitrust claims arising therefrom, in each case, to the extent based upon or attributable to the Patents in the Exclusively Licensed IP for which and to the extent Dynavax is responsible for the Prosecution and Maintenance under Article 8;

*except*, in each case above, to the extent such Claim arose out of or resulted from or is attributable to the negligence, recklessness or wrongful intentional acts or omissions of GSK and/or its Affiliate, or their respective directors, officers, employees and agents.

11.3 Procedure. In the event that any person (an "Indemnitee") entitled to indemnification under Section 11.1 or Section 11.2 is seeking such indemnification, such Indemnitee shall (i) inform, in writing, the indemnifying Party of the claim as soon as reasonably practicable after such Indemnitee receives notice of such claim, (ii) permit the indemnifying Party to assume direction and control of the defense of the claim (including the sole right to settle it at the sole discretion of the indemnifying Party, taking into consideration in good faith any reasonable concerns or objections raised by the Indemnitee; provided that such settlement does not impose any obligation on, or otherwise adversely affect, the Indemnitee or other Party), (iii) cooperate as reasonably requested (at the expense of the indemnifying Party) in the defense of the claim, and (iv) undertake all reasonable steps to mitigate any loss, damage or expense with respect to the claim(s).

### 11.4 Insurance.

11.4.1 Dynavax's Insurance Obligations. Dynavax shall maintain, at its cost, with effect from [\*] (including, without limitation, all Products and any product based thereon) [\*] hereunder and during the Term thereafter, adequate insurance against liability and other risks associated with its activities contemplated by this Agreement, including but not limited to its Clinical Trials and its indemnification obligations herein, in such amounts and on such terms as are customary for prudent practices in the biotechnology industry for the activities to be conducted by it under this Agreement; provided, however, that in no event shall such insurance coverage be less than [\*] per claim and annual aggregate prior to the date of first administration of any Compound or Product to humans by GSK or any Dynavax Product to humans by Dynavax hereunder, and further provided that such coverage is increased to at least [\*] at least [\*] before Dynavax or its Affiliate or Sublicensee initiates the First Commercial Sale of any Dynavax Product hereunder. Dynavax shall furnish to GSK evidence of such insurance upon request.

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**11.4.2** *GSK's Insurance Obligations*. GSK hereby represents and warrants to Dynavax that it is self-insured against liability and other risks associated with its activities and obligations under this Agreement in such amounts and on such terms as are customary for prudent practices for large pharmaceutical companies in the pharmaceutical industry for the activities to be conducted by it under this Agreement. GSK shall furnish to Dynavax evidence of such self-insurance upon request.

11.5 LIMITATION OF LIABILITY. EXCEPT FOR A BREACH OF ARTICLE 9 OR FOR CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 11 OR AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER DYNAVAX NOR GSK, NOR ANY OF THEIR AFFILIATES OR SUBLICENSEES, WILL BE LIABLE TO THE OTHER PARTY TO THIS AGREEMENT, ITS AFFILIATES OR ANY OF THEIR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

### **ARTICLE 12**

### TERM AND TERMINATION

- **12.1 Term; Expiration**. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 12, shall expire as follows:
- **12.1.1** On a Product-by-Product and country-by-country basis, on the date of the expiration of all payment obligations under this Agreement with respect to such Product in such country;
- 12.1.2 In its entirety upon the expiration of all payment obligations under this Agreement with respect to the last Product in all countries in the Territory; and
- **12.1.3** On a Program-by-Program basis when no Compound or Product is being Researched, Developed or commercialized by either Party hereunder with Commercially Reasonable Efforts pursuant to a given Dynavax Program or GSK Development Program or Dynavax Development Program, [\*].

The period from the Effective Date until the date of expiration of this Agreement in its entirety, or as the case may be, until the date of the expiration of this Agreement in part with respect to a given Product or Program, may be referred to herein as the "**Term.**"

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### 12.2 Termination for Cause.

12.2.1 Termination for Material Breach. Either Party (the "Non-breaching Party") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement, either on a Program-by-Program basis or in its entirety, as may be appropriate to protect the interest of the Non-breaching Party arising from such alleged breach, in the event the other Party (the "Breaching Party") shall have materially breached or defaulted in the performance of any of its material obligations hereunder either with respect to a particular Program or the Agreement as a whole, and such default shall have continued for [\*] after written notice thereof was provided to the Breaching Party by the Non-breaching Party, such notice describing with particularity and in detail the alleged material breach. Subject to Section 12.2.2, any such termination of the Agreement under this Section 12.2 shall become effective at the end of such [\*] period, unless the Breaching Party has cured any such breach or default prior to the expiration of such [\*] period, or if such breach is not susceptible to cure within such [\*] period even with the use of Commercially Reasonable Efforts, the Non-Breaching Party's right to termination shall be suspended only if and for so long as the Breaching Party has provided to the Non-Breaching Party a written plan that is reasonably calculated to effect a cure, such plan is acceptable to the Non-Breaching Party (or to the arbitrators, in the event of arbitration pursuant to Section 13.1), and the Breaching Party commits to and does carry out such plan. The right of either Party to terminate this Agreement, or a portion of this Agreement, as provided in this Section 12.2 shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default.

**12.2.2** *Disagreement.* If the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party that seeks to dispute that there has been a material breach may contest the allegation in accordance with Section 13.1. The cure period for any allegation made in good faith as to a material breach under this Agreement will run from the date that written notice was first provided to the Breaching Party by the Nonbreaching Party, but shall be suspended pursuant to Section 13.2.

**12.3 GSK Unilateral Termination Rights.** GSK shall have the right, at its sole discretion and without any penalty or liability, exercisable at any time during the Term, to terminate this Agreement either in its entirety or on a Program-by-Program basis, for any reason or for no reason at all, upon (a) [\*] prior written notice to Dynavax if such notice is given [\*], in each case subject to the obligations set forth in Section 12.5.2.

### 12.4 Termination for Insolvency.

12.4.1 Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party proposes a written agreement of composition or extension of substantially all of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed [ \* ] Calendar Days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment of substantially all of its assets for the benefit of creditors.

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12.4.2 All rights and licenses granted under or pursuant to any section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code (the "Bankruptcy Code") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

#### 12.5 Effect of Termination or Expiration.

**12.5.1** *Upon Expiration.* Following the expiration of the Term pursuant to Section 12.1, the following terms shall apply:

(a) Subject to the terms and conditions of this Agreement, following expiration of the Term with respect to a GSK Product in a country pursuant to Section 12.1.1, GSK shall have an exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the Exclusively Licensed IP, to continue to make, have made, use, sell, offer to sell and import such GSK Product in the Field in such country, for so long as it continues to do so.

**(b)** Subject to the terms and conditions of this Agreement, following expiration of the Term with respect to a Dynavax Product in a country pursuant to Section 12.1.1, Dynavax shall have an exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the GSK Development IP and GSK's interest in the Collaboration IP, solely to continue to make, have made, use, sell, offer to sell and import such Dynavax Product in the Field in such country, for so long as it continues to do so.

(c) Subject to the terms and conditions of this Agreement, following expiration of the Term with respect to this Agreement in its entirety pursuant to Section 12.1.2, GSK shall have an exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the Exclusively Licensed IP, to continue to make, have made, use, sell, offer to sell and import GSK Products in the Field in the Territory, for so long as it continues to do so.

(d) Subject to the terms and conditions of this Agreement, following expiration of the Term with respect to this Agreement in its entirety pursuant to Section 12.1.2, Dynavax shall have an exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the GSK Development IP and GSK's interest in the Collaboration IP, solely to continue to make, have made, use, sell, offer to sell and import Dynavax Products in the Field in the Territory, for so long as it continues to do so.

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| <b>12.5.2</b> Upon Unilateral Termination by GSK.              | . In the event of a unilateral termination of this Agreement in its entirety or any Program | by |
|--|---|----|
| GSK pursuant to Section 12.3, the following terms shall apply: |   |    |

- (a) Notwithstanding anything contained herein to the contrary, all licenses granted to GSK with respect to Compounds and GSK Products in the terminated Program (or, in the case of termination of the entire Agreement, all Compounds and GSK Products) shall terminate, each such GSK Product shall be deemed to be a Dynavax Product, and the terms and conditions of Sections 5.3, 6.5 and 6.6 shall apply with respect to such Dynavax Products;
- **(b)** as of the date of notice of such termination, GSK shall not be required to use Commercially Reasonable Efforts to progress any GSK Products in the terminated Program(s) under this Agreement, and as of the effective date of such termination, GSK will cease any and all Development and commercialization activities with respect to Compounds included in a terminated Program (or in the case of termination of the entire Agreement, all Programs); provided, however, that nothing in this Section 12.5.2 is intended to limit GSK's obligations under Section 12.5.5;
- (c) All unexercised Options with respect to the terminated Program(s) as of the date that Dynavax receives such notice from GSK shall be cancelled and of no force and effect;
- (d) With respect to any Compound in a terminated Program (or in the case of termination of the entire Agreement, all Programs), GSK shall grant, and hereby grants, to Dynavax an exclusive right and license, with the right to grant sublicenses, under GSK's (including its Affiliate's and Sublicensee's) interest in any Collaboration IP and GSK Development IP [\*], solely to Develop, make, have made, use, sell, offer to sell and import such Compound as a Dynavax Product in the Field in the Territory, for so long as it continues to do so, subject to the royalty obligations set forth in Sections 6.5 and 6.6; and
- (e) In the event of termination of the Agreement in its entirety or on a Program-by-Program basis pursuant to Section 12.3, all of Dynavax's and GSK's respective [\*] with respect to TLRs in the terminated Program(s) shall immediately terminate and no longer be of any force or effect.
- **12.5.3** *Upon Termination by GSK for Cause or Dynavax's Insolvency.* In the event of a termination of this Agreement in its entirety or any Program by GSK pursuant to Section 12.2.1 for a material breach by Dynavax, or the entire Agreement pursuant to Section 12.4:
- (a) All Options with respect to the terminated Programs (or in the case of termination of the entire Agreement, all Options) that are unexercised as of the effective date of termination shall be cancelled and of no force and effect;
- **(b)** For each terminated Program for which GSK has not exercised the Option, [\*]. GSK will [\*], and (ii) all [\*] shall not apply. Notwithstanding the above, in no event shall [\*].

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| (c) In the case of termination by GSK of a Program for an uncured material breach or insolvency of Dynavax that occurred                                 |
|--|
| after the exercise by GSK of its Option with respect to such Program or a termination by GSK of the entire Agreement, in each case pursuant to Section   |
| 12.2.1 or Section 12.4, GSK shall retain any license granted in Section 4.2.1 with respect to the Compounds in each terminated Program for which GSK has |
| already exercised its Option, provided that GSK continues to comply with all [*] with respect to such GSK Products, except that [*].                     |

- (d) In the event of termination of the Agreement in its entirety or on a Program-by-Program basis by GSK pursuant to Section 12.2.1, all of GSK's exclusivity obligations under Article 7 with respect to the TLRs in the terminated Program(s) shall [\*], but the exclusivity obligations of Dynavax under Article 7 shall continue in full force and effect as follows: (i) [\*] Dynavax's obligations shall continue in accordance with the terms of Article 7, and (ii) [\*] Dynavax's obligations under Article 7 shall [\*].
- **(e)** GSK shall no longer have any obligations with respect to diligence or to use Commercially Reasonable Efforts with respect to (i) any Compounds or GSK Products resulting from any Dynavax Program or GSK Development Program that was terminated by GSK pursuant to Section 12.2.1, or (ii) all Compounds and GSK Products if the entire Agreement was terminated pursuant to Section 12.2.1.
- **(f)** Notwithstanding the foregoing, to the extent that termination by GSK of this Agreement for insolvency of Dynavax does not, as a result of the outcome of bankruptcy or insolvency proceedings, result in GSK having the right to exercise its rights pursuant to the foregoing Section 12.5.3(b) or (c), then GSK shall also have the remedy set forth in Section [\*] shall have occurred.
- **12.5.4** *Upon Termination by Dynavax for Cause or GSK's Insolvency.* In the event that Dynavax terminates a Program or this Agreement pursuant to Section 12.2.1 or the entire Agreement pursuant to Section 12.4:
- (a) All Options with respect to the terminated Programs (or in the case of termination of the entire Agreement, all Options) that are unexercised as of the effective date of termination shall be cancelled and of no force and effect. For clarity, GSK shall not be permitted to exercise any Option after receiving notice of Dynavax's termination under Section 12.2.1 without Dynavax's prior written consent, unless and until Dynavax agrees, or it is determined pursuant to the process set forth under Section 13.1 or Section 13.2, that GSK has cured the applicable breach in a timely manner or GSK has not been in material breach or GSK has been in breach but the matter has been resolved in favor of allowing GSK to exercise its Option;
- **(b)** With respect to any Compound in a terminated Program (or in the case of termination of the entire Agreement, any Program), at Dynavax's option, GSK will grant, and hereby grants, to Dynavax an exclusive right and license, with the right to grant sublicenses, under GSK's (including its Affiliate's and Sublicensee's) interest in any Collaboration IP and any GSK Development IP [\*], solely to Develop, make, have made, use, sell, offer to sell and import such Compounds as Dynavax

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Products in the Field in the Territory, for so long as it continues to do so, subject to the royalty obligations as set forth in Sections 6.5 and 6.6; and

- (c) In the event of termination by Dynavax of the Agreement in its entirety or on a Program-by-Program basis, the respective [\*] of Dynavax and GSK under Article [\*] shall continue in full force and effect for [\*].
- **12.5.5** *Obligations of GSK with Respect to Compounds in Dynavax Products.* Upon termination of a Program or this Agreement by Dynavax pursuant to Section [\*], or termination of a Program or this Agreement by GSK pursuant to Section [\*]:
- (a) GSK shall complete any ongoing trials of GSK Products with regard to [\*]; provided, however, that if Dynavax terminates this Agreement pursuant to Section [\*], Dynavax may instead elect to have GSK (i) transition oversight of such ongoing trials to Dynavax as soon as reasonably practicable and (ii) [\*] associated with Dynavax completing such trials with regard to [\*]. Notwithstanding the foregoing, GSK may prematurely suspend or terminate any such trial if (A) a priori protocol defined stopping rules are met for safety or efficacy or (B) unacceptable safety signals are observed by GSK or the Data and Safety Monitoring Board with respect to the Product or related Compound that present an unacceptable risk to patients participating in such trials;
- **(b)** GSK shall promptly return to Dynavax, [\*], all Information and materials transferred by Dynavax to GSK with respect to each such Compound and shall transfer stocks of Product [\*] to Dynavax;
- (c) GSK shall transfer to Dynavax, at Dynavax's request, any and all data and Information pertaining directly and solely to the applicable Compounds that are necessary for the continued Development and commercialization of such Compounds in its possession and other related materials, including without limitation copies of all clinical study data and results, and all other Information and the like developed by or for the benefit of GSK relating to such Compounds and other documents to the extent directly and solely relating to such Compounds that are necessary in the continued Development and commercialization of such Compounds as Dynavax Products (including without limitation material documents and agreements relating to the sourcing, manufacture, promotion, distribution, sale or use of a Product) throughout the Territory; and
- **(d)** GSK shall wherever practical assign (and where not practical shall permit use of the same) to Dynavax any and all regulatory filings relating to such Compounds, including, without limitation, any NDAs.

#### 12.6 Accrued Rights; Surviving Provisions of the Agreement.

12.6.1 Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration including the payment obligations under Article 6 hereof and any and all damages

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or remedies arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.

12.6.2 The provisions of Articles 9, 11 and 13 and Sections 2.10, 4.2 (in accordance with Section 12.5, as applicable), 5.3 (in accordance with Section 12.5, as applicable), 6.10, 8.1, 10.4, 12.5 and 12.6 as well as any applicable definitions in Article 1, shall survive the termination or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive indefinitely. Article 9 shall survive for a period of [\*].

#### **ARTICLE 13**

#### **MISCELLANEOUS**

- **13.1 Dispute Resolution.** Unless otherwise expressly provided in Section 3.1.4 as not being subject to further review under Section 13.1, in the event of a dispute arising under this Agreement between the Parties, either Party shall have the right to refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 13.1 within [\*] days of referring such dispute to the Executive Officers, either Party may have the given dispute settled by binding arbitration pursuant to Section 13.2.
- **13.2 Arbitration Request**. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which Party must cure a breach of this Agreement becomes suspended as to any breach that is the subject matter of the dispute.
- 13.2.1 Additional Issues. Within [\*] Business Days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.
- **13.2.2** *No Arbitration of Patent Issues.* Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patents covering the manufacture, use, importation, offer for sale or sale of Products shall be submitted to a court of competent jurisdiction in the country in which such patent rights were granted or arose.

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13.2.3 Arbitration Procedure. Any arbitration pursuant to this Article 13 will be held in the continental United States at a location to be agreed by the Parties and under the rules of the American Arbitration Association ("AAA"). The arbitration will be governed by the United States Arbitration Act, 9 U.S.C. §§ 1-16, to the exclusion of any inconsistent state laws. The Parties shall mutually agree the rules to govern discovery and the rules of evidence for the arbitration. In the event the parties fail to agree promptly to such rules, The United States Federal Rules of Civil Procedure will govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted by three (3) arbitrators who are knowledgeable in the subject matter at issue in the dispute. The Parties will attempt to select three (3) arbitrators that are each acceptable to both Parties. In the event the Parties fail to agree promptly on three mutually-acceptable arbitrators, one (1) arbitrator will be selected by Dynavax, one (1) arbitrator will be selected by GSK, and the third arbitrator will be selected by mutual agreement of the two (2) arbitrators selected by the Parties. The arbitrators may proceed to an award, notwithstanding the failure of either Party to participate in the proceedings. The arbitrators shall, within fifteen (15) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall be limited in the scope of their authority to resolving only the specific matter which the Parties have referred to arbitration for resolution and shall not have authority to render any decision or award on any other issues. The arbitrators shall be authorized to award compensatory damages, but shall not be authorized to award punitive, special, consequential, or any other similar form of damages, or to reform, modify or materially change this Agreement. The arbitrators also shall be authorized to grant any temporary, preliminary or permanent equitable remedy or relief the arbitrators deem just and equitable and within the scope of this Agreement, including, without limitation, an injunction or order for specific performance. The award of the arbitrators shall be the sole and exclusive remedy of the Parties, except for those remedies that are set forth in this Agreement or which apply to a Party by operation of the applicable provisions of this Agreement, and the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrators, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrators. Judgment on the award rendered by the arbitrators may be enforced in any court having competent jurisdiction thereof, subject only to revocation on grounds of fraud or clear bias on the part of the arbitrators. Notwithstanding anything contained in this Section 13.2 to the contrary, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in order to seek to enforce the instituting Party's rights hereunder through specific performance, injunction or similar equitable relief.

**13.2.4** *Costs.* Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges and travel expenses).

**13.2.5** *Preliminary Injunctions.* Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisions basis, pending the decision of the arbitrators on the ultimate merits of any dispute.

13.2.6 Confidentiality. All proceedings and decisions of the arbitrators shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 9.

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- **13.3 Governing Law.** This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of the State of Delaware without reference to conflicts of laws principles.
- 13.4 Assignment. Either Party may assign this Agreement to any Affiliate of such Party without the consent of the other Party; provided, that such Party provides the other Party with written notice of such assignment and remains fully liable for the performance of such Party's obligations hereunder by such Affiliate. Further, each Party may assign this Agreement without the consent of the other Party to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets to which this Agreement relates; provided, that such Party provides the other Party with written notice of such assignment; provided further, that if such assignment involves a transaction in which Dynavax: (a) merges or consolidates with any other entity (other than a wholly-owned subsidiary of Dynavax); or (b) effects any other transaction or series of transactions, such that the stockholders of Dynavax immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving entity following the closing of such merger, consolidation, other transaction or series of transactions (a "Change of Control Event"), then Dynavax will notify GSK prior to the closing of such Change of Control Event, and [\*]. The terms and conditions of this Agreement shall be binding upon and shall inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 13.4 shall be null and void.
- **13.5 Performance Warranty**. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all the covenants, terms, conditions and agreements set forth in this, Agreement by its Affiliate(s) and Sublicensees.
- **13.6 Force Majeure**. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation (other than a payment obligation) of this Agreement when such failure or delay is due to *force majeure*, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, *force majeure* is defined as causes beyond the control of the Party, including, without limitation, acts of God; acts, regulations, or laws of any government; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event Dynavax or GSK, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled for up to a maximum of ninety (90) days, after which time Dynavax and GSK shall promptly meet to discuss in good faith how to best proceed in a manner that maintains and abides by the Agreement. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any *force majeure*.
- **13.7 Notices.** Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

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If to Dynavax, addressed to: Dynavax Technologies Corporation

2929 Seventh Street, Suite 100

Berkeley, CA 94710

Attention: Chief Executive Officer Telephone: (510) 665-4601 Facsimile: (510) 848-1376

with a copy to: Cooley Godward Kronish LLP

Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306 Attention: Glen Y. Sato, Esq. Telephone: (650) 843-5502 Facsimile: (650) 849-7400

If to GSK, addressed to: Attention: Business Development

GlaxoSmithKline Greenford Road Greenford Middlesex

UB6 0HE, United Kingdom

[ \* ]

with a copy to: Attention: Vice President and Associate General Counsel,

R&D Legal Operations GlaxoSmithKline

2301 Renaissance Boulevard

Mail Code RN0220 King of Prussia, PA 19406

[\*]

or to such other address for such Party as it shall have specified by like notice to the other Parties, provided that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3<sup>rd</sup>) Business Day after such notice or request was deposited with the U.S. Postal Service.

**13.8 Export Clause.** Each Party acknowledges that the laws and regulations of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other party in any form without the appropriate United States and foreign government licenses.

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- **13.9 Waiver**. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.
- **13.10 Severability**. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.
- **13.11 Entire Agreement.** This Agreement, together with the Schedules and Exhibits hereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understanding between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.
- **13.12 Independent Contractors**. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.
- **13.13 Headings; Interpretation**. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Further, in this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable.
- **13.14 Books and Records**. Any books and records to be maintained under this Agreement by a Party or its Affiliates or Sublicensees shall be maintained in accordance with U.S. generally accepted accounting principles in the case of Dynavax, and shall be maintained in accordance with International Financial Reporting Standards (IFRS) in the case of GSK, consistently applied, except that the same need not be audited.
- **13.15 Further Actions**. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

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- **13.16 Parties in Interest**. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the Parties hereto and their respective successors, heirs, administrators and permitted assigns.
- **13.17 Construction of Agreement**. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.
- **13.18 Supremacy**. In the event of any express conflict or inconsistency between this Agreement and a Development Plan or any Schedule or Exhibit hereto, the terms of this Agreement shall control. The Parties understand and agree that the Schedules and Exhibits hereto are not intended to be the final and complete embodiment of any terms or provisions of this Agreement, and are to be updated from time to time during the Term, as appropriate and in accordance with the provisions of this Agreement.
- **13.19 Counterparts**. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

\*\_\*\_\*

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**IN WITNESS WHEREOF,** and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

#### **Dynavax Technologies Corporation**

By: /s/ Dino Dina
Name: Dino Dina, M.D.

Title: President and CEO

#### **Glaxo Group Limited**

By: /s/ Paul Williamson

Name: Paul Williamson

Title: For and on behalf of Edinburgh

Pharmaceutical Industries Limited

Corporate Director

#### **EXHIBIT A**

[\*]

#### **EXHIBIT E**

#### [ \* ] Criteria

Dose Ranging – Safety and [\*].

It is expected that the [\*] would be i) in healthy volunteers undergoing immunological challenge relevant to the mechanism or ii) in patients with gain in function/activation of the relevant pathway, where a short term intervention is anticipated to be able to demonstrate efficacy on the mechanism.

Maximum anticipated duration of treatment − 2-4 weeks,

Maximum anticipated subjects – placebo, and 3 dose group

 $4 \times 10-15$  subjects = 40-60 subjects.

Depending on the mechanism and disease [\*] could be within FTIH study (including FTIH being in patients) or could follow a separate FTIH study

Evidence for Proof of Mechanistic Effect

Quantitative measurements of multiple immunological parameters will be taken from treated subjects for example, cytokine/chemokine profiles, leukocyte CD antigens and genome-wide gene expression profiling, impact on signaling pathways and if appropriate on tissue pathology. Assays will be performed to determine extent of target binding. Criteria for positive [\*] would be based on evidence of pharmacology, PK/PD relationship and resulting relevant mechanistic efficacy, with supportive trends in clinical markers if the study is within a patient population.

The desired goal is to achieve an early proof of pharmacological and mechanistic activity to develop PD markers, PK/PD modeling, and safety information, that will allow informed decision-making on progression of the asset and selection of smaller numbers of dose groups for the larger Phase IIb PoC trial, thus enabling that study to be up to 25% smaller]

#### **EXHIBIT F**

#### **Press Release**





#### GlaxoSmithKline and Dynavax Announce Worldwide Strategic Alliance

-- Developing First-in-Class Endosomal TLR Inhibitors for

Autoimmune and Inflammatory Diseases --

London, United Kingdom, Philadelphia, PA, and Berkeley, CA – December 16, 2008 – GlaxoSmithKline (LSE and NYSE: GSK) and Dynavax Technologies Corporation (NASDAQ: DVAX) today announced a worldwide strategic alliance to discover, develop and commercialize novel inhibitors of endosomal Toll-like Receptors (TLRs) for the treatment of immuno-inflammatory diseases. TLRs are key receptors of the innate immune system that can induce strong inflammatory responses.

Under the terms of the alliance, Dynavax will receive an initial payment of \$10 million for which GSK will receive an exclusive option over four programs targeting autoimmune and inflammatory diseases such as lupus, psoriasis, and rheumatoid arthritis.

"Our alliance with GSK provides an opportunity to create an entirely new product franchise for Dynavax," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "Our TLR inhibitors have the potential to create significant value for our newest collaborator GSK as well as for our stockholders. Alliances with major pharmaceutical companies have enabled Dynavax to establish a diverse pipeline of innovative products, while contributing valuable cash for our programs."

Dynavax is to conduct research and early clinical development in up to four programs and is eligible to receive future potential development and commercialization milestones totaling approximately \$200 million per program. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK will carry out further development and commercialization of these products. Dynavax will receive tiered, up to double-digit royalties on sales and has retained an option to co-develop and co-promote one specified product.

Dynavax has pioneered a new approach to treating autoimmune and inflammatory diseases with its first-in-class oligonucleotide-based endosomal TLR inhibitors, called immunoregulatory sequences (IRS). Dynavax's lead inhibitor drug candidate, DV1079, is a bifunctional inhibitor of TLR7 and TLR9, and is expected to enter clinical development in the fourth quarter of 2009.

"We are committed to using our expertise, in collaboration with Dynavax, to research and develop new therapeutics that can improve the lives of patients with conditions like systemic lupus erythematosus, psoriasis and rheumatoid arthritis," commented Jose Carlos Gutierrez-Ramos, Ph.D., Senior Vice President and Head of

the Immuno-Inflammation Centre of Excellence for Drug Discovery at GSK. "Dynavax is a recognized pioneer in the scientific community for its innovation of endosomal TLR inhibitors which prevent immune signaling in autoimmune and inflammatory diseases."

#### **Dynavax Conference Call**

Dynavax will webcast a conference call today at 9:00 a.m. ET (6:00 a.m. PT) to discuss this alliance. The live and archived webcast can be accessed by visiting the investor relations section of the Company's Web site at http://investors.dynavax.com/events.cfm.

#### **About TLR Inhibitors**

Dynavax's endosomal TLR inhibitors are a novel class of oligonucleotides, called immunoregulatory sequences (IRS), that specifically inhibit the TLR-induced inflammatory response associated with autoimmune and inflammatory diseases. Preclinical data from animal model studies show Dynavax's TLR inhibitors block IFN-alpha and also reduce symptoms in multiple autoimmune diseases models, such as lupus, inflammatory skin disorders, and rheumatoid arthritis.

#### **About Dynavax**

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified, well-funded pipeline of novel Toll-like Receptor (TLR) product candidates. Based on Dynavax's proprietary technology platform, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax's product programs are supported by global partnerships with leading pharmaceutical companies such as Merck & Co., Inc., GlaxoSmithKline, and AstraZeneca AB, as well as funding from Symphony Dynamo, Inc. and the National Institutes of Health. For more information visit www.dynavax.com.

#### **Dynavax Forward-Looking Statement**

This press release contains "forward-looking statements," including statements related to the potential value of payments that may be received under our collaboration with GSK, the anticipated development of our inhibitors of endosomal TLRs, the future responsibilities of the parties under the collaboration agreement and Dynavax's ability to perform under the terms of the collaboration agreement. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including difficulties or delays in discovery or development, initiation and completion of preclinical or clinical studies, the results of those studies and the impact of those results on the initiation and completion of subsequent studies and issues arising in the regulatory process; achieving our GSK collaborative agreement objectives; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

#### About GlaxoSmithKline

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information, visit GlaxoSmithKline at www.gsk.com.

#### GlaxoSmithKline Forward-Looking Statement

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.

#### **Dynavax Contacts:**

Michael Ostrach VP and Chief Business Officer 1-510-665-7257 mostrach@dynavax.com

Amy Figueroa Investor Relations and Corporate Communications 1-510-665-7211 afigueroa@dynavax.com

#### **GSK Contacts:**

| GSK UK Media enquiries:                      | Philip Thomson                                    | (020) 8047 5502                                       |
|--|---|---|
|  | Stephen Rae<br>Alice Hunt<br>Gwenan White         | (020) 8047 5502<br>(020) 8047 5502<br>(020) 8047 5502 |
| GSK US Media enquiries:                      | Nancy Pekarek<br>Mary Anne Rhyne<br>Sarah Alspach | (215) 751 7709<br>(919) 483 2839<br>(215) 751 7709    |
| GSK European Analyst/<br>Investor enquiries: | David Mawdsley                                    | (020) 8047 5564                                       |
| investor enquires.                           | Sally Ferguson<br>Gary Davies                     | (020) 8047 5543<br>(020) 8047 5503                    |
| GSK US Analyst/<br>Investor enquiries:       | Tom Curry   | (215) 751 5419  |

###

#### **SCHEDULE 8.6**

#### Agreements Granting Third Parties Rights to Prosecute and Maintain Dynavax Compound Patents

Research Collaboration and License Agreement, dated as of September 1, 2006, by and between AstraZeneca AB and Dynavax, as amended from time to time.

Novated and Restated Technology License Agreement, dated as of April 18, 2006, by and among Dynavax, Symphony Dynamo, Inc. and Symphony Holdings LLC, as amended from time to time

#### **SCHEDULE 10.2**

#### **Rights Granted to Third Parties Under Dynavax Compound IP**

Research Collaboration and License Agreement, dated as of September 1, 2006, by and between AstraZeneca AB and Dynavax, as amended from time to time.

Novated and Restated Technology License Agreement, dated as of April 18, 2006, by and among Dynavax, Symphony Dynamo, Inc. and Symphony Holdings LLC, as amended from time to time

## DYNAVAX TECHNOLOGIES CORPORATION AMENDED AND RESTATED 2004 NON-EMPLOYEE DIRECTOR OPTION PROGRAM AND

#### AMENDED AND RESTATED 2005 NON-EMPLOYEE DIRECTOR CASH COMPENSATION PROGRAM

EFFECTIVE APRIL 14, 2005 AMENDED February 4, 2014 (REVISION VERSION 5.0)

## ARTICLE I ESTABLISHMENT AND PURPOSE OF THE PROGRAM

#### 1.1 Establishment of Program

The Dynavax Technologies Corporation 2004 Non-Employee Director Option Program, as revised herein, including the Non-Employee Director Cash Compensation Program (collectively, the "Director Program") is adopted pursuant to the Dynavax Technologies Corporation 2011 Equity Incentive Plan (the "2011 Plan"), in addition to the terms and conditions set forth below, is subject to the provisions of the Plan.

#### 1.2 Purpose of Program

The purpose of the Director Program is to enhance the ability of the Company to attract and retain directors who are not Employees ("Non-Employee Directors") through an Option and Cash Compensation program.

#### 1.3 Effective Date of the Program

The Director Program is effective as of the Registration Date, and as revised on February 4, 2014.

### ARTICLE II DEFINITIONS

Capitalized terms in this Director Program, unless otherwise defined herein, have the meaning given to them in the Plan.

#### ARTICLE III OPTION TERMS

#### 3.1 Date of Grant and Number of Shares

Effective April 14, 2005, a Non-Qualified Stock Option to purchase 20,000 shares of Common Stock shall be granted (the "Initial Grant") to each Non-Employee Director and 30,000 shares shall be granted to the Non-Employee Chairman of the Board (the "Initial Grant"), and such Initial Grant to be made to Non-Employee Directors elected or appointed to the Board upon the date each such Non-Employee Director first becomes a Non-Employee Director.

In addition, immediately following each annual meeting of the Company's stockholders, commencing with the annual meeting of the Company's stockholders in 2012, each Non-Employee Director who continues as a Non-Employee Director following such annual meeting shall be granted a Non-Qualified Stock Option to purchase 17,500 shares of Common Stock (a "Subsequent Grant"). Based on the Non-Employee Director's election date, the first subsequent grant shall be pro-rated as follows:

| Service Period from Election Date    | Option Grant Schedule         |
|--------------------------------------|-------------------------------|
| More than 10 up to 12 months         | 100% of grant (17,500 shares) |
| More than 7 months, but less than 10 | 75% of grant (13,125 shares)  |
| More than 4 months, but less than 7  | 50% of grant (8,750 shares)   |
| More than 1 month, but less than 4   | 25% of grant (4,375 shares)   |

Each such Subsequent Grant shall be made on the date of the annual stockholders' meeting in question.

#### 3.2 Vesting

Each Initial Grant of Common Stock subject to the Option under the Director Program shall vest twenty-five percent (25%) twelve (12) months after the grant date and an additional twenty-five percent (25%) of the shares of Common Stock subject to the Option shall vest on each yearly anniversary of the grant date thereafter, such that the Option will be fully exercisable four (4) years after its date of grant.

Each Subsequent Grant under the Director Program will vest and become exercisable as to all of the shares of Common Stock subject to the Option twelve (12) months after the grant date.

#### 3.3 Exercise Price

The exercise price per share of Common Stock of each Initial Grant and Subsequent Grant shall be one hundred percent (100%) of the Fair Market Value per share on the date of grant.

#### 3.4 Corporate Transaction/Change in Control

Each Option under the Director Program shall be subject to the provisions of Section 9 of the 2011 Plan relating to the exercise or termination of the Option in the event of a Corporate Transaction or a Change in Control.

#### 3.5 Other Terms

The Administrator (the "Dynavax Board of Directors") of the Plan shall determine the remaining terms and conditions of the Options awarded under the Program.

## ARTICLE IV CASH COMPENSATION TERMS

#### 4.1 Annual Fees

Each Non-Employee Director currently on the Company's board, or elected in 2012 and thereafter, shall receive an annual retainer fee of \$40,000. The Chairman of the Board shall receive an annual retainer fee of \$65,000. Such annual retainer fees will be paid in quarterly installments at the end of each fiscal quarter where such person is an active director of the board ("active director" requires attendance at 75% of the annually scheduled board meetings) and is inclusive of 5 scheduled board meetings.

#### 4.2 [Intentionally Removed]

#### 4.3 Committee Meeting Fees

The Chairman of the Audit Committee shall receive an annual retainer of \$20,000. Each member of the audit committee shall receive an annual retainer of \$7,500.

The Chairman of the Compensation Committee shall receive an annual retainer of \$15,000. Each member of the compensation committee shall receive an annual retainer of \$7,000.

The Chairman of the Nominating and Governance Committee shall receive an annual retainer of \$10,000. Each member of the nominating committee shall receive an annual retainer of \$5,000.

Such annual retainer fees will be paid quarterly at the end of each fiscal quarter where such person is an active Chairman or member of the Committee and an Active Director.

#### 4.4 Travel and Related Costs

Reasonable travel and related costs associated with attending Board and committee meetings shall be reimbursed. The Board member needs to submit proper documentation for reimbursement.



Berkeley, California 94710

#### Sent via USPS

February 27, 2013

**David Novack** 

Re: Amended Employment Terms

Dear David:

Dynavax Technologies Corporation ("Dynavax" or the "Company") is pleased to offer you the position of Senior Vice President, Operations and Quality, on the following terms.

You will be responsible for providing strategic leadership and operational management oversight of the technical operations and quality organizations of the Company, and other duties as assigned. You will report to J. Tyler Martin, MD, President and Chief Medical Officer and work at our facility located at 2929 Seventh Street, Suite 100 in Berkeley, California. The Company may change your position, duties, and work location from time to time as it deems necessary.

Your compensation will be \$25,000 per month, annualized to \$300,000, less payroll deductions and all required withholdings. You will be paid semi-monthly, and will be eligible for the following standard Company benefits: medical insurance for yourself and your family (there will be an employee contribution for dependent coverage), 12 holidays per year, life insurance, disability insurance, long-term care insurance, Flexible Spending Account, 401(k), and Employee Stock Purchase Plan. The Company may modify compensation and benefits from time to time as it deems necessary.

Personal time off is not accrued or tracked for members of the executive team. The attached Personal Time-Off Policy highlights the time off you have to use each year. Also, you and your eligible dependents will be covered under the Exec-U-Care medical reimbursement plan. This plan supplements your health insurance up to \$50,000 per employee or family unit for unreimbursed medical expenses during a calendar year. Please be advised, the Exec-U-Care plan will be available through year end December 2013 due to the Health Care Reform Act.

As a member of the executive team, you are eligible for a 50% target annual incentive bonus, based on your performance measured against corporate, individual and project milestones to be proposed by the company and mutually agreed upon by the parties by no later than thirty days from your start date with Dynavax. Annual incentive bonus targets are typically reviewed and approved by the Company's Compensation Committee in the first quarter of the following year, and payout of the bonuses are at the discretion of the Company's board of directors. To receive an incentive bonus payment, an eligible participant in the program must be an active employee on the date the bonus is paid.

The Company will grant you a stock option to purchase 300,000 shares of the Common Stock of the Company, with an exercise price equal to the fair market value of the Common Stock on the date of grant. This stock option is subject to all of the terms and conditions set forth in the applicable award agreement and applicable stock incentive plan. Your stock option grant of 300,000 shares of the Common Stock of the Company will vest as follows: 25% of the Shares subject to the Option shall vest twelve months after the Vesting Commencement Date, and 1/48 of the Shares subject to the Option shall vest on the last day of each month thereafter, provided that vesting shall cease upon termination of your continuous service to the Company.

PHONE: 510-848-5100 TOLL-FREE: 877-848-5100 FAX: 510-848-1327 WWW.DYNAVAX.COM



Berkeley, California 94710

As agreed upon, we will provide you with a \$75,000 sign-on bonus, less applicable withholding deductions. This bonus will be paid in the pay cycle after completing four weeks of full-time employment. If you voluntarily terminate your employment within twelve months of your start date, this amount must be reimbursed to the Company.

This offer is subject to your submission, no later than three days after your employment begins, of an I-9 form and satisfactory documentation regarding your identification and right to work in the United States.

Your employment is contingent upon the acceptable results of a background check, including Social Security number, education, and employment verification. Any falsification of an applicant's employment history or educational background will result in withdrawal of the offer and/or termination of employment, if hired.

As an employee of the Company, you will be expected to abide by Company rules and regulations, and to sign and comply with a Proprietary Information and Inventions Agreement, which prohibits unauthorized use or disclosure of the Company's proprietary information.

Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt salaried employee, you will be expected to work additional hours as required by the nature of your work assignments.

You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. This at-will employment relationship cannot be changed except by written agreement signed by a Company officer.

The employment terms in this letter and your management continuity and severance agreement supersede any other agreements or promises made to you by anyone, whether oral or written.

Please sign and date one copy of this letter and return it in the enclosed envelope to Cecilia Vitug, VP of Human Resources, if you accept our offer of employment. A mutually acceptable start date can be agreed upon after you accept our offer of employment.

David, we look forward to a positive reply and productive and enjoyable work relationship if you join the Company. Sincerely.

/s/ Cecilia Vitug Cecilia Vitug Vice President, Human Resources & Corporate Services

# Accepted: /s/ David Novack David Novack March, 6, 2013 Date



2929 Seventh Street, Suite 100 Berkeley, California 94710

#### **Hand Delivered**

July 11, 2013

Rob Janssen, MD

Dear Rob:

Congratulations on your promotion to Vice President and Chief Medical Officer. Your new compensation package will be:

|  | Effective July 9, 2013  |   |
|--|---|---|
|  | New   | Current   |
| Base Salary Any salary increase you may be eligible to receive in January 2014 will be pro-rated based on your mid-year 2013 salary increase.  | \$350,000<br>(\$14,583.33 per pay period)<br>Breakdown:<br>• \$10,918 (or 4% merit)<br>• \$16,132 (or 5.9% promo)<br>\$27,050 | \$300,000<br>(\$12,500 per pay period)  |
| Target Annual Bonus Your 2013 target bonus will be pro-rated based on the change in your salary mid- year. This means your target bonus from January 1 through June 30, 2013 will be based on 40% of your previous salary - \$300,000. The target bonus from July 1 through December 31, 2013, will be based on 50% of your current salary of \$350,000. | 50% or \$175,000<br>Weight Distribution is:<br>Corporate 50%<br>Individual 50%  | 40% or \$120,000<br>Weight Distribution was:<br>Corporate 40%<br>Individual 50% |
| <b>Total Target Cash Compensation</b>  | \$525,000   | \$420,000   |
| Performance-Based Equity Grant 150,000 restricted stock units (RSU)  |   |   |

Your RSU is subject to all of the terms and conditions set forth in the 2011 Equity Plan and shall vest as follows:

- 50,000 shares shall vest upon submission of the safety study data in support of the CRL.
- · 100,000 shall vest upon approval of HEPLISAV.

The Board and the Administrator of the Plan shall have full power and authority to interpret or modify the above vesting terms in their discretion.

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2929 SEVENTH STREET, SUITE 100 BERKELEY, CALIFORNIA 94710

Your award is subject to the terms of the Dynavax 2011 Incentive Stock Option Plan. You will receive the restricted stock unit agreement in the next few weeks.

The at-will employment terms of your offer letter dated March 19, 2010 and your current management continuity and severance agreement remains the same.

Rob, I look forward to working with you in ensuring Dynavax's success today and in the future. If you have any questions regarding the terms of your compensation, see Cecilia Vitug. Please sign and return one copy of this letter to Cecilia.

Sincerely,

/s/ Eddie Gray Eddie Gray Chief Executive Officer

#### Acknowledgement:

/s/ Rob Janssen July 12, 2013

Rob Janssen/Date



2929 SEVENTH STREET, SUITE 100 BERKELEY, CALIFORNIA 94710

#### Hand-delivered

February 4, 2014

David L. Johnson

Re: Employment Terms

Dear Dave:

Dynavax Technologies Corporation is pleased to offer you the position of Vice President and Chief Accounting Officer on the following terms.

You will provide leadership and management oversight on a global basis for accounting, financial planning and analyses, external reporting, and information technologies, and other duties as assigned. You will report to Michael Ostrach – Vice President, General Counsel, Chief Business and Principal Financial Officer and work at our facility located at 2929 Seventh Street, Suite 100 in Berkeley, California. The Company may change your position, duties, and work location from time to time as it deems necessary.

Your compensation will be \$22,916.66 per month, annualized to \$275,000.00, less payroll deductions and all required withholdings. You will be paid semi-monthly, and will be eligible for the following standard Company benefits: medical insurance for yourself and your qualified dependents (there will be an employee contribution for dependent coverage), 12 holidays per year, life insurance, disability insurance, long-term care insurance, Flexible Spending Account, 401(k), and Employee Stock Purchase Plan. The Company may modify compensation and benefits from time to time as it deems necessary.

Personal time-off (PTO) is not accrued and tracked for members of the executive team and management at the director and senior director level. The attached Personal Time-Off Policy highlights the time you have available to use each year. The Company may modify compensation and benefits from time to time as it deems necessary.

You are eligible to participate in the Company's Annual Incentive Bonus program with a target incentive bonus of 40% of your annual base salary. Payment of the Company's annual incentive bonus is determined by achievement of your individual goals and the Company's approved corporate goals. To receive an annual incentive bonus payment, an eligible participant in the program must be an active employee in good standing on the date the bonus is paid. Payout of bonuses is at the discretion of the Dynavax Board of Directors. If your start date is in the 4<sup>th</sup> quarter of the current calendar year, you are eligible effective the 1<sup>st</sup> day of the New Year.

The Company will grant you a stock option to purchase 200,000 shares of the Common Stock of the Company, with an exercise price equal to the fair market value of the Common Stock on the date of grant. This stock option is subject to all of the terms and conditions set forth in the applicable award agreement and applicable stock incentive plan. Your stock option grant 200,000 shares of the Common Stock of the Company will vest as follows: 25% of the Shares subject to the Option shall vest twelve months after the Vesting Commencement Date, and 1/48 of the Shares subject to the Option shall vest on the last day of each month, provided that vesting shall cease upon termination of your continuous service to the Company.

As we discussed, the Company is developing a corporate continuity and severance program. You will be eligible for benefits defined for vice presidents.

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2929 SEVENTH STREET, SUITE 100 BERKELEY, CALIFORNIA 94710

This offer is subject to your submission of a completed and signed I-9 form within 3 days of your employment, along with satisfactory documentation(s) verifying your identification and right to work in the United States.

Your employment is contingent upon the acceptable results of a background check, including but not limited to your Social Security number, education, employment, and criminal verification. Any falsification in your employment history, educational and criminal background will result in withdrawal of the offer and/or termination of employment, if hired.

As an employee of the Company, you will be expected to abide by Company rules and regulations, and to sign and comply with a Proprietary Information and Inventions Agreement, which prohibits unauthorized use or disclosure of the Company's proprietary information.

Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt salaried employee, you will be expected to work additional hours as required by the nature of your work assignments.

You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. This at-will employment relationship cannot be changed except by written agreement signed by a Company officer.

The employment terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written.

Dave, your employment will be converted from consultant to regulatory full-time employee effective February 5, 2014. We look forward to a productive and enjoyable work relationship.

Sincerely,

Accepted:

/s/ Cecilia Vitug Cecilia Vitug VP of Human Resources

## /s/ David Johnson David L. Johnson February 4, 2014 Date

Exhibit 10.87

#### AMENDMENT TO RESEARCH AND DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT

- 1. This letter agreement (the "Letter Agreement") is made as of the date of last signature below (the "Letter Agreement Effective Date") by and between Dynavax Technologies Corporation ("Dynavax") and Glaxo Group Limited ("GSK"). Reference is made to the Research and Development Collaboration and License Agreement dated 15 December 2008 between Dynavax and GSK, as amended (the "Research Agreement"). Capitalized terms used but not defined in this Letter Agreement shall have the meaning assigned to such terms in the Research Agreement.
- 2. In accordance with clause 2.3 of the Research Agreement, the Initial Research Term is scheduled to expire on 15 December 2013. Dynavax and GSK hereby agree that the Research Term should be extended, as described in greater detail below, and that simultaneously specific elements of the Research Agreement shall be modified and clarified.
- 3. The Research Term shall be extended until the conclusion of the Option Deadline Period for the TLR 7/9 Program (DV1179), which shall be either the date on which GSK exercises its Option to license in accordance with clause 4.1.3 or the Option expires or is terminated under clause 4.1.4.
- 4. Dynavax's obligation to provide [\*\*\*] Back-up Compounds, defined in clause 5.2.1, is modified as follows. GSK acknowledges that [\*\*\*] required Back-up Compounds [\*\*\*] by Dynavax, [\*\*\*], the originally-adopted Compound for the TLR 7/9 Program, [\*\*\*]. Before the end of the Option Deadline Period, GSK will decide whether [\*\*\*] Back-up Compound [\*\*\*], assuming the Option is exercised, and will notify Dynavax of the decision on the date of Option exercise. GSK agrees that, if [\*\*\*], the Compound [\*\*\*]. GSK will review the preclinical characterization work completed as of the date of this Letter Agreement and within [\*\*\*] of the Letter Agreement Effective Date will either: (1) notify Dynavax whether the data are [\*\*\*] and are therefore [\*\*\*] to [\*\*\*]; or (2) will delineate the [\*\*\*] present in the [\*\*\*]. If [\*\*\*] are identified necessitating [\*\*\*] efforts for [\*\*\*], Dynavax will use Commercially Reasonable Efforts to complete such activities during, and if the Option for DV1179 is exercised after, the Research Term, but in no event shall be obligated to continue such work for more than [\*\*\*] following [\*\*\*].
- 5. As of the Letter Agreement Effective Date, exclusivity obligations applicable to Dynavax pursuant to clause 7.1 shall be modified to exclude from the prohibited activities any Research, Development, or Commercialization of TLR 7/9 inhibitors, other than DV1179 and any adopted Back-up Compound, in the [\*\*\*] field. For the avoidance of doubt, such activities shall not be considered to be part of a Dynavax Program under the Research Agreement and any inventions that may occur will not be considered Collaboration Know-How or Collaboration Patents. Data generated by Dynavax during the Research Term related to [\*\*\*] applications of TLR 7/9 inhibitors [\*\*\*] and, if GSK exercises the Option to license DV1179, GSK will [\*\*\*] for the further development of DV1179 [\*\*\*] or [\*\*\*] defined under the Research Agreement. If requested by GSK and authorized by the JSC, Dynavax may include DV1179 and/or a Back-up Compound in [\*\*\*] Research activities that occur during the Research Term.
- 6. The obligation described in clause 2.6.4 for [\*\*\*] with the [\*\*\*] that [\*\*\*] is eliminated. In the event that the [\*\*\*] for the [\*\*\*] and all Development activities required [\*\*\*], all [\*\*\*] be [\*\*\*].
- 7. This Letter Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware without reference to conflicts of law principles. Any dispute arising from the performance or breach hereof shall be treated in accordance with Sections 13.1 and 13.2 of the Research Agreement.
- 8. This Letter Agreement forms an addition to the Research Agreement and the Research Agreement shall remain in full force and effect according to its terms and shall not be modified except as set out in this Letter Agreement.

1217869 v4/HN

IN WITNESS HEREOF, and intending to be legally bound hereby, the Parties have caused this Letter Agreement to be executed by their duly authorized representatives as of the Letter Agreement Effective Date.

#### **Dynavax Technologies Corporation**

#### **Glaxo Group Limited**

/s/ Michael Ostrach
Name: Michael Ostrach

Title: Vice President
Date: December 13, 2013

/s/ Beverley Carr Name: Beverley Carr

Title: VP Business Development Date: 13th December 2013

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1217869 v4/HN

Exhibit 10.88

#### AMENDMENT No. 5

This Amendment No. 5 (the "Amendment") to the Agreement dated 1 September 2006 by and between

- (1) ASTRAZENECA AB, a company incorporated in Sweden under no. 556011-7482 with offices at S-151 85 Södertälje, Sweden ("AstraZeneca"); and
- (2) DYNAVAX TECHNOLOGIES CORPORATION, a Delaware corporation with offices at 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753, USA ("Dynavax")

as amended (the "Agreement") is made effective as of the 7 day of January 2014 (the "Amendment Effective Date").

#### **Recitals**

WHEREAS, the Research Term has expired and the Joint Research has been completed; and

WHEREAS, under the Agreement AstraZeneca has nominated AZD 1419 as a Lead CD; and

WHEREAS, under the Agreement AstraZeneca has the responsibility, as set forth therein, for Developing Candidate Drugs selected and Commercialising Products and Commercialisation: and Commercialisation: and

WHEREAS, in furtherance of the Development of AZD 1419 the Parties agreed in Amendment Agreement No 4 that Dynavax would carry out a certain portion of the Development, primarily consisting of the Phase I Study and the Phase II a Study, as more closely described and on the terms set forth in the Amendment No4; and

WHEREAS, the Parties now wish to further change the allocation of the Development work to be carried out between the Parties under the Agreement by in particular agreeing that after completion by Dynavax of the Phase I Study AstraZeneca shall assume responsibility for carrying out the Phase II a Study and all subsequent Development of AZD 1419 under the Agreement as envisaged prior to the adoption of the changes set out in Amendment No 4; and

The Parties as a consequence desire to further amend, modify and restate certain terms and conditions of the Agreement.

#### Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Amendment, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

#### Definitions.

Any capitalized term not separately defined in this Amendment shall have the meaning ascribed to it in the Agreement.

#### **Modifications**

2.1 The following Sections shall be inserted immediately after Section 1.123 of the Agreement as new Sections 1.124 through 1.138.

- 1.124 'Aggregate Amount" has the meaning defined in Section 9.4.1.
- 1.133 **'Phase I Study**' means the clinical study regarding AZD 1419 with the design, endpoint, number of subjects and time plan described, and otherwise as described, in the Amendment Development Phase I Study Plan, attached hereto as a Schedule 1
- 1.134 'Phase II a Studies' means the clinical study regarding AZD 1419 with the design, endpoint, number of subjects and time plan described, and otherwise as described, in the Amendment Development Phase II a Study Plan, attached hereto as a Schedule 2.
- 1.139 **'Dynavax Development Work**' means the Phase I Study."
- 2.2 The Sections 8.2.B and 8.2.C are hereby deleted and shall be replaced by new Sections 8.2.B and 8.2.C as set out below:
- "8.2. B Notwithstanding what is stated in Section 8.2 (as amended); Dynavax shall be responsible for completing the Dynavax Development Work in accordance with what is stated herein. Upon completion of the Dynavax Development Work and payment of the milestone in Section 9.4.1 (as amended), such Regulatory Documentation, Regulatory Filing and, as applicable, Health Registration Approvals, generated by Dynavax shall be transferred to AstraZeneca free of charge in a format useful and suitable for AstraZeneca for the purpose of being be able to continue the Development and carry out Commercialisation in accordance with this Agreement.
- 8.2.D Immediately upon completion of the Dynavax Development Work, or at any time before such completion as decided from time to time by the JSC, Dynavax shall make available and transfer to AstraZeneca any Dynavax Know-How, compounds and other materials generated by or on behalf of Dynavax, solely or jointly with AstraZeneca or any Third Party, in the course of the Dynavax Development Work in a format useful and suitable for AstraZeneca to be able to continue the Development and carry out Commercialisation in accordance with this Agreement."
- 2.3 For the avoidance of doubt all milestone payments set out in the deleted Sections 8.9.B and 8.9.C (other than those which have already been paid as at the Amendment Effective Date) will not become due.
- 2.4 Sections 9.4.1 and 9.4.2 are hereby deleted and shall be replaced by new Sections 9.4.1 and 9.4.2 as set out below:
  - "9.4.1 Five million four hundred thousand U.S. Dollars (\$5,400,000) upon signature of this Amendment Agreement No 5. Upon completion of the Phase I Study and payment of the milestone in Section 9.4.1, such Regulatory Documentation, Regulatory Filing and, as applicable, Health Registration Approvals, shall be transferred to AstraZeneca free of charge in a format useful and suitable for AstraZeneca for the purpose of being be able to continue the Development and carry out Commercialisation in accordance with this Agreement.
  - 9.4.2 [\*\*\*] US Dollars (\$[\*\*\*]) within [\*\*\*] days following [\*\*\*].

#### 3 Amendment Effective Date

This Amendment shall become effective on the Amendment Effective Date.

#### **4 Entire Agreement**

This Amendment, together with the Agreement, constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. The Agreement together with this Amendment supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement, as amended. Each Party confirms that it is not relying on any statements, representations, warranties or covenants of any person (whether a Party to this Agreement or not) except as specifically set out in the Agreement as amended. Nothing in this Amendment is intended to limit or exclude any liability for fraud. All Schedules referred to in this Amendment are intended to be and are hereby specifically incorporated into and made a part of the Agreement. The Parties hereby agree that subject to the modifications specifically stated in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

#### Execution AB"

THIS AGREEMENT IS EXECUTED by the authorised representatives of the Parties as of the date first written above.

SIGNED for and on behalf of SIGNED for and on behalf of

AstraZeneca AB (publ) Dynavax Technologies Corporation

/s/ Maarten Kraan/s/ Eddie GrayMaarten KraanEddie Gray

VP iMed RIA CEO

| Schedule 1 | L |
|------------|---|
|------------|---|

#### Phase 1 Study Plan

[\*\*\*]

#### Schedule 3

#### Phase II a Study Plan [to be agreed]1\*

[\*\*\*]

|   | For the 12 Months Ended December 31 |          |    |          |    |          |     |          |    |          |
|---|-------------------------------------|----------|----|----------|----|----------|-----|----------|----|----------|
|   |                                     | 2013     |    | 2012     |    | 2011     |     | 2010     |    | 2009     |
|   | _                                   |          |    |          |    | (In t    | hou | sands)   |    |          |
| Earnings  |                                     |          |    |          |    |          |     |          |    |          |
| Loss from continuing operations before income taxes                     | \$                                  | (66,720) | \$ | (69,949) | \$ | (48,597) | \$  | (57,308) | \$ | (15,127) |
| Fixed charges   |                                     | 509      |    | 2,795    |    | 2,420    |     | 2,341    |    | 796      |
| Amount attributable to noncontrolling interest in Symphony Dynamo, Inc. |                                     | -        |    | -        |    | -        |     | -        |    | 4,233    |
| Earnings, as defined  | \$                                  | (66,211) | \$ | (67,154) | \$ | (46,177) | \$  | (54,967) | \$ | (10,098) |
| Fixed charges:  |                                     |          |    |          |    |          |     |          |    |          |
| Interest expense  | \$                                  | -        | \$ | 2,351    | \$ | 1,957    | \$  | 1,654    | \$ | 124      |
| Estimated interest component of rent expenses                           |                                     | 509      |    | 444      |    | 463      |     | 687      |    | 672      |
| Total fixed charges   | \$                                  | 509      | \$ | 2,795    | \$ | 2,420    | \$  | 2,341    | \$ | 796      |
| Deficiency of earnings available to cover fixed charges (1)             | _                                   | (66,720) | _  | (69,949) | _  | (48,597) | _   | (57,308) | _  | (15,127) |

 $<sup>\</sup>textbf{(1)} : \ Adjusted \ earnings, \ as \ described \ above, \ were \ insufficient \ to \ cover \ fixed \ charges \ in \ each \ year.$ 

<u>List of Subsidiaries</u> Rhein Biotech GmbH Dynavax International, B.V.

#### **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Form S-3 Nos. 333-164254, 333-165663, 333-169576, 333-175645 and 333-191610) of Dynavax Technologies Corporation and in the related Prospectuses,
- (2) Registration Statement (Form S-3/A Nos. 333-164254 and 333-191610) of Dynavax Technologies Corporation and in the related Prospectus, and
- (3) Registration Statements (Form S-8 Nos. 333-113220, 333-136345, 333-145094, 333-152819, 333-157741, 333-164255, 333-171552 and 333-190313) pertaining to the 1997 Equity Incentive Plan, the 2004 Stock Incentive Plan, the 2004 Employee Stock Purchase Plan, the 2010 Employment Inducement Award Plan and/or the 2011 Equity Incentive Plan of Dynavax Technologies Corporation; of our reports dated March 10, 2014, 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) of Dynavax Technologies Corporation for the year ended December 31, 2013.

/s/ Ernst & Young LLP

Redwood City, California March 10, 2014

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

#### CERTIFICATIONS

#### I, Eddie Gray, 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 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 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 likely 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 the 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/ EDDIE GRAY   |
|-----|--|
|     | Eddie Gray Chief Executive Officer (Principal Executive Officer) |

Date: March 10, 2014

#### Rule 13a-14(a) Certification of Principal Financial Officer

#### **CERTIFICATIONS**

#### I, Michael Ostrach, 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:
  - 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 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 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 likely 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 the 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
  - 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/ MICHAEL OSTRACH

Michael Ostrach
Vice President
(Principal Financial Officer)

Date: March 10, 2014

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

- I, Eddie Gray, 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, 2013 as filed with the Securities and Exchange Commission on the date hereof and to which this Certificate is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and
  - (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of March, 2014.

| By: | /s/ EDDIE GRAY                |  |  |  |
|-----|-------------------------------|--|--|--|
|     | Eddie Gray                    |  |  |  |
|     | Chief Executive Officer       |  |  |  |
|     | (Dringing) Evenutive Officer) |  |  |  |

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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

- I, Michael Ostrach, 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 31,2013 as filed with the Securities and Exchange Commission on the date hereof and to which this Certificate is attached as Exhibit 32.2 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and
  - (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned have set their hands hereto as of the 10<sup>th</sup> day of March, 2014.

| By: | /s/ MICHAEL OSTRACH |  |  |
|-----|---------------------|--|--|
|     | Michael Ostrach     |  |  |
|     | Vice President      |  |  |

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.