

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended **December 31, 2017**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: **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

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 No

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

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

Indicate by check mark 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 (§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 No

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2017 as reported on the NASDAQ Capital Market, was approximately \$491,000,000. 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 March 1, 2018, the registrant had outstanding 61,681,017 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2018 Annual Meeting of Stockholders are incorporated by reference into Part III, Items 10-14 of this Form 10-K. The Definitive Proxy Statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2017.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our ability to successfully commercialize HEPLISAV-B™, develop and timely achieve regulatory approval for SD-101, DV281 and our other early stage compounds, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, 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, strategies, 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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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. References herein to “we,” “our,” “us,” “Dynavax” or the “Company” refer to Dynavax Technologies Corporation and its subsidiary.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a fully-integrated biopharmaceutical company focused on leveraging the power of the body’s innate and adaptive immune responses through toll-like receptor (“TLR”) stimulation. Our first commercial product, HEPLISAV-B™ (Hepatitis B Vaccine (Recombinant), Adjuvanted), was approved by the United States Food and Drug Administration (“FDA”) in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology products are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1 safety study.

OUR TECHNOLOGY

Toll-like Receptor Immune Modulation Platform

Toll-like receptors are a family of transmembrane proteins that play a vital role in innate immunity and subsequent adaptive immunity. Signaling through these receptors is triggered by the binding of a variety of pathogen-associated molecules and is essential to generation of innate immunity. The innate immune response is, in effect, the first line of defense against viruses, bacteria and other potential pathogens. The innate response also initiates and regulates the generation of an adaptive immune response composed of highly specific antibodies and T cells. Our research is focused primarily on stimulation of a subset of TLRs that have evolved to recognize bacterial and viral nucleic acids.

Our research has resulted in the identification of proprietary synthetic oligonucleotides (short segments of DNA), that mimic the activity of microbial DNA and selectively activate one of these important receptors, TLR9. These are called CpG

oligonucleotides – CpGs for short – referring to the presence of specific nucleotide sequences containing the CG base pair. In addition, we are developing compounds that activate two other important innate receptors, TLR7 and TLR8. These TLR agonists are able to stimulate or modify immune responses as single agents and can synergize with other classes of immunotherapeutic agents. In combination with tumor antigens or vaccines, these TLR agonists can substantially enhance and prolong protective immune responses. Thus, this portfolio of novel and potent activators opens multiple opportunities for expanding the scope of cancer immunotherapy, enhancing the efficiency of vaccines and modulating allergic diseases.

OUR STRATEGY

- Commercialize HEPLISAV-B, initially in the United States, to generate cash flows to support continued development of TLR-based immuno-oncology therapeutics and new vaccines
- Demonstrate the versatility of our immuno-oncology platform by assessing efficacy in multiple tumor types and in combination with a range of modalities through clinical development of product candidates in three areas:
 - Intratumoral SD-101 in combination with anti-PD-1 therapies in melanoma, head and neck squamous cell carcinoma (“HNSCC”) and additional tumor types
 - Combinations of SD-101, DV281 or our other TLR agonists in combination with agents other than anti-PD-1/L-1 alone, including other immuno-modulatory agents or chemotherapy
 - TLR9 or TLR7/8 agonists designed for targeted delivery beyond intratumoral injection

HEPLISAV-B

The Company's first commercial product, HEPLISAV-B (Hepatitis B Vaccine, (Recombinant), Adjuvanted), was approved on November 9, 2017 by the FDA for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

HEPLISAV-B combines 1018, our proprietary TLR9 agonist adjuvant, and recombinant hepatitis B surface antigen (“rHBsAg” or “HBsAg”) that is manufactured by Dynavax GmbH, our wholly-owned subsidiary in Düsseldorf, Germany. In Phase 3 trials, HEPLISAV-B demonstrated higher rates of protection with fewer doses than a currently approved hepatitis B vaccine and a similar adverse event profile. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S.

About Hepatitis B

Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis of the liver, liver cancer and death. Hepatitis B virus is an extremely infectious and potentially deadly virus. It can be spread through the exchange of body fluids such as semen or blood, and is 50 to 100 times more infectious than HIV.

Hepatitis B can be either acute or chronic. Acute hepatitis B virus infection is a short-term illness that occurs within the first six months after exposure to the hepatitis B virus. Acute infection can — but does not always — lead to chronic infection. Chronic hepatitis B virus infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body.

There is no cure for hepatitis B, but the disease can be prevented through effective vaccination. The World Health Organization (“WHO”) and Centers for Disease Control and Prevention (“CDC”) have set a goal to eliminate all viral hepatitis infections, including hepatitis B, globally by 2030, and are calling for a continued commitment to increase services to eliminate hepatitis.

Increasing Prevalence

Worldwide, an estimated 257 million people are living with hepatitis B, including 850,000 in the United States, where an estimated 20,000 new infections occur each year. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.

Disease Transmission

In adults, sexual transmission of hepatitis B may occur, particularly in unvaccinated men who have sex with men and heterosexual persons who have multiple sex partners or contact with sex workers. Transmission of the virus may also occur through the reuse of needles and syringes either in healthcare settings or among persons who inject drugs. Infection also can occur during medical, surgical and dental procedures, through tattooing or the use of razors contaminated with infected blood.

Prevention in Adults with Effective Vaccination

Adult vaccination to prevent hepatitis B is recommended by the CDC Advisory Committee on Immunization Practices (“ACIP”) for many at-risk populations, including certain healthcare and public safety workers, people with diabetes and travelers. The ACIP recommendation includes adults with the following risks:

- **Environmental Related Risk** - Health care and first responders, travelers, persons who are in close contact with hepatitis B infected patients, residents and staff of facilities for developmentally disabled and those who work with HBV-infected primates or HBV in the lab;
- **Increased Risk or Severity of Disease due to Chronic Conditions** - Adults with diabetes, end stage renal disease, HIV and chronic liver disease;
- **Behavioral Risk** – Men who have sex with men, persons with multiple sex partners, STD clinic patients, inmates, IV drug users.

Protection Against Hepatitis B

The approval of HEPLISAV-B was based on data from three Phase 3 non-inferiority trials of nearly 10,000 adult participants who received HEPLISAV-B. These pivotal studies compared HEPLISAV-B administered in two doses over one month to Engerix-B administered in three doses over a six-month schedule. Results from HBV-23, the largest Phase 3 trial, which included 6,665 participants, showed that HEPLISAV-B demonstrated a statistically significantly higher rate of protection of 95% compared with 81% for Engerix-B. Across the three clinical trials, the most common local reaction was injection site pain (23% to 39%). The most common systemic reactions were fatigue (11% to 17%) and headache (8% to 17%).

Commercialization of HEPLISAV-B in the United States

Dynavax has worldwide commercial rights to HEPLISAV-B. There are three approved hepatitis B vaccines in the U.S.: Engerix-B and Twinrix® from GlaxoSmithKline plc (“GSK”) and Recombivax-HB® from Merck & Co. (“Merck”).

We commenced shipments of HEPLISAV-B in January 2018. Currently, the total U.S. sales for adult hepatitis B vaccines is approximately \$270 million annually. We are targeting approximately 25% of the total vaccine outlets that we believe represents approximately 80% of hepatitis B vaccine sales with our recently deployed field sales force team of approximately 60 people across 10 regions. On February 21, 2018, the CDC’s ACIP voted unanimously in favor of including HEPLISAV-B on its list of ACIP recommended products for use to vaccinate adults against hepatitis B.

In late 2012 the 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 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.

DEVELOPMENT PROGRAMS

Our pipeline of product candidates includes the following. Each clinical stage program is discussed in further detail below.

Product Candidate		Indication(s)	Stage of Development	Partner
Immuno-oncology				
SD-101		Melanoma	Phase 2	Merck & Co ¹
SD-101		Head and Neck Squamous Cell Carcinoma	Phase 2	Merck & Co ¹
DV281		Non-small Cell Lung Cancer	Phase 1	
DV230F		Liver Tumors	Preclinical	
DV1001 and others		TLR7/8 agonists for oncology	Preclinical	
Immune-Mediated Diseases				
AZD1419		Asthma Disease Modification	Phase 2	AstraZeneca AB ²
¹ Under clinical collaboration with Merck & Co. Dynavax is funding the study and maintains all commercial rights to SD-101. ² AstraZeneca AB is funding and conducting the study and has licensed worldwide commercial rights.				

Immuno-oncology

Immuno-oncology is a rapidly advancing field that focuses on modulating the immune system to develop or enhance anti-tumor activities in order to control growth or eliminate tumors. The industry is exploring multiple strategies and technologies aimed at enhancing and prolonging anti-tumor immune responses and inhibiting the actions of multiple immune checkpoints that limit the effectiveness of anti-tumor responses. Agents that inhibit two of these immune checkpoints, CTLA-4 and the PD-1/PD-L1 interaction, have been approved for a number of cancer indications. These checkpoint inhibitors represent a major advance in cancer treatment, yet a majority of patients fail to respond to these inhibitors used as single agents. In many instances, it appears that the failure to respond correlates with anti-tumor activity that remains inadequate even with checkpoint blockade. Thus, a major opportunity in immuno-oncology is the development of immunostimulatory approaches that increase the number, location and functional state of tumor-reactive cytotoxic T cells, enabling remission and durable control of tumor growth.

Through our expertise in TLR biology we have designed compounds that stimulate multiple innate mechanisms, activating a cascade of anti-tumor activities including stimulating the tumor microenvironment, generating tumor specific T cells and initiating a systemic distribution of those cells to all tumor sites. These compounds were specifically designed to stimulate multiple pathways of tumor killing through type 1 interferon induction and highly efficient stimulation of antigen presenting functions of plasmacytoid dendritic cells.

Our clinical development strategy for immuno-oncology applications is based on two key principles. The first is that immune activation by TLR agonists will be significantly more effective when focused on the tumor than when administered as a systemic therapy. This has been shown in many studies with mouse tumor models and has been confirmed in pioneering academic studies of intratumoral injection of CpGs in lymphoma patients. These studies indicate TLR9 stimulation applied locally allows optimal concentrations of the CpG to be achieved at the site of highest concentrations of tumor antigens and T cells that recognize those antigens. Local stimulation of innate anti-tumor mechanisms, such as Natural Killer cells, should enhance release of tumor antigens and locally induced chemokine gradients can lead to enhanced recruitment of additional tumor-reactive T cells.

The second principle is the development of combinations that have complementary mechanisms of action and have the potential for synergistic, rather than additive clinical effects. An example is our development of combination treatment of intra-tumoral SD-101 with the PD-1 inhibitor, pembrolizumab. Pembrolizumab releases anti-tumor T cells from one of the most potent of the immune checkpoints, while intratumoral SD-101 generates both greater numbers and more highly functional cytotoxic T cells directed against tumor cells. We have published studies showing the mechanisms of this synergy in mouse tumor models.

We are developing our initial immuno-oncology product candidates, SD-101 and DV281, to eventually be combined with a variety of immunotherapies when activation of an anti-tumor immune response is desirable. We are targeting combinations with checkpoint inhibitors that offer activities synergistic with TLR9 stimulation, with an initial focus on approved checkpoint inhibitors in indications that have generally low response rates and would provide a clear path to approval. As a result, in 2015, we began our first combination trial in metastatic melanoma with SD-101, our novel intratumoral TLR9 agonist, in combination with KEYTRUDA® (pembrolizumab), an anti-PD1 therapy approved for metastatic melanoma, under a clinical collaboration with Merck. We have expanded this trial to include head and neck squamous cell carcinoma, another approved indication for KEYTRUDA. Under the terms of the agreement, Dynavax is sponsoring and funding the trial, Merck is supplying KEYTRUDA at no cost and the data and intellectual property are shared. Each party has agreed that during the term of the study, it will not conduct a combination study with any third party that involves the combination of the two classes of compounds.

We also are conducting a study of DV281 in lung cancer in combination with an anti-PD-1 therapy and there are ongoing and planned studies to support our strategy to develop SD-101 and DV281 in combination with multiple checkpoint inhibitors and other agents in multiple indications. Studies sponsored by us include the following:

SD-101 – TLR9 Agonist for intratumoral injection

Our lead cancer immunotherapy candidate is SD-101, a C Class CpG TLR9 agonist that was selected for characteristics optimal for treatment of cancer, including high interferon induction. Directly injecting SD-101 into a tumor site optimizes its effect by ensuring proximity to tumor-specific antigens. In animal models, SD-101 demonstrated significant anti-tumor effects at both the injected site and at distant sites.

SD-101 in combination with KEYTRUDA® (pembrolizumab) in Melanoma

In October 2015, we initiated a Phase 1/2 multicenter clinical trial to assess the safety and potential efficacy of intratumoral SD-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with advanced or metastatic melanoma. The study includes patients who have disease that is progressing while receiving an anti-PD-1 therapy and patients who are naïve to anti-PD-1 therapy.

In June 2017, we reported results from the Phase 1 dose escalation part of the study, evaluating 19 patients for efficacy and 22 patients for safety. In patients naïve to anti-PD-1 treatment, the overall response rate was 100% (seven of seven evaluable patients) and the complete response rate was 29%. Of the 12 evaluable patients who had progressed on prior anti-PD-1/L1 monotherapy prior to enrollment, two partial responses were observed (16.7%). The combination of the two drugs was generally well tolerated with no dose-limiting toxicities.

In early 2017, we completed the initial dose escalation phase and began the Phase 2 expansion phase of the trial with the objective of enrolling approximately 60 patients with malignant melanoma who are naïve to anti-PD-1/L1 therapy and 25 patients with progressive disease following previous anti-PD-1/L1 therapy.

SD-101 in combination with KEYTRUDA® (pembrolizumab) in Head and Neck Squamous Cell Carcinoma

Based on the initial results from the combination of SD-101 and KEYTRUDA in melanoma, we expanded the combination study with KEYTRUDA to include a Phase 2 trial seeking to enroll approximately 34 patients with recurrent or metastatic head and neck squamous cell cancers who are naïve to anti-PD-1/L1 therapy and 25 patients with progressive disease following anti-PD-1/L1 therapy.

DV281 – Inhaled TLR 9 agonist for lung cancer

We pioneered the development of inhaled TLR9 agonists. We designed and developed AZD1419, an inhaled TLR9 agonist for asthma under a collaboration with AstraZeneca AB (“AstraZeneca”) and that product candidate is currently being

evaluated by AstraZeneca in a Phase 2 clinical trial in asthma patients. Based on this experience and our SD-101 research, we are developing a TLR9 agonist, DV281, designed for delivery to lung cancer patients as an inhaled aerosol.

Although we continue to advance the strategy of focused delivery of a CpG in studies with intratumoral injection of SD-101, there are many tumor types for which direct, repeated injection is not feasible. Non-small cell lung cancer (“NSCLC”) represents one such challenge. This major type of lung cancer is known to respond to a variety of immunotherapy approaches and several inhibitors of the PD-1/PD-L1 checkpoint pathway have been approved for NSCLC. Yet response rates to these agents remain low. A strategy for focused delivery to lung tumors is direct administration to the lung by inhalation. To accomplish this, we have developed DV281, a novel investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. DV281 is similar in biological activity and mechanism of action to SD-101, but has been optimized for administration as an aerosol.

Studies in preclinical animal models of lung cancer show that this direct delivery of DV281 to tumor-bearing lungs results in induction of interferons and cytokines and infiltration of T cells, responses similar to those observed after intratumoral injection of SD-101. Animal models also demonstrate synergy of inhaled DV281 with anti-PD1 antibodies in reducing tumor burden and generating a systemic and durable anti-tumor response. Inhaled DV281, delivered by a nebulizer, entered clinical trials for NSCLC, in combination with anti-PD-1 therapy, in October, 2017.

AZD1419 for Asthma

AZD1419 is being developed for the treatment of asthma pursuant to a collaboration with AstraZeneca. 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 to type-1 helper T cells.

A Phase 1a study of AZD1419 demonstrated its safety and tolerability in healthy subjects. The study also produced dose-dependent induction of genes by endogenous interferon, as measured in sputum, indicating presence of the drug at the target site and expected activity. AstraZeneca is conducting a Phase 2a trial in asthma patients.

Vaccine Adjuvants

Our vaccine research to date has focused on the use of TLR9 agonists as novel adjuvants. Different TLR9 agonist molecules are taken up within different endosomes within target cells, stimulating different signaling pathways. CpG B-Class TLR9 agonists, such as our 1018 vaccine adjuvant, are selectively taken up by late endosomes (more mature endosomes also known as multivesicular bodies), resulting in signaling that leads to release of cytokines necessary for T cell activation and establishing long-term immunity but with modest induction of interferon alpha. TLR9 stimulation also helps generate memory T Helper 1 (“Th1”) cells that can stimulate the immune system to induce long-lasting effects. As a result, TLR9 adjuvanted vaccines induce a specific Th1 immune response and durable levels of protective antibodies. We are evaluating additional candidates to leverage our 1018 adjuvant in additional vaccines. We are collaborating with the Serum Institute of India, to develop adjuvanted vaccines using 1018. Our initial joint program is an improved pertussis vaccine.

INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and know-how, 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, Europe, Japan 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, 2017, our intellectual property portfolio included over 30 issued U.S. patents, over 240 issued or granted foreign patents and over 30 additional pending U.S. and foreign patent applications claiming compositions containing TLR agonists or antagonists, methods of use, and/or methods of manufacture thereof.

We have an issued U.S. patent covering the TLR agonist contained in our HEPLISAV-B vaccine that will expire in June 2018, for which we filed a Patent Term Extension Application in January 2018, which, if obtained, would extend the expiration date by five years. We have two issued patents relating to certain uses of HEPLISAV-B that expire in 2032. We have issued patents expiring in 2023 and covering compositions such as SD-101 and their uses in the U.S. and in several major European and other countries. We own or have an exclusive license to U.S. and foreign patents and 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 patents varies in accordance with provisions of applicable local law, but typically is 20 years from the 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 2018 to 2038.

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, 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 competitors, Merck and GSK, are exclusive licensees of broad patents covering HBsAg, a component of HEPLISAV-B. We have a non-exclusive license to the patent licensed to Merck. The three patents licensed to GSK expire July 31, 2018. With our having commercialized HEPLISAV-B, we may become involved in litigation or licensing in respect of these patents.

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, Inc. 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 in 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.

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 vaccine adjuvants, cancer immunotherapy and autoimmune and inflammatory diseases. There are many commercially available products for the prevention and 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, competes directly with conventional three-dose marketed vaccines Engerix-B from GSK as well as Recombivax-HB marketed by Merck. 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 competes against Twinrix, a multivalent vaccine marketed by GSK for protection against hepatitis B and hepatitis A.

Our cancer immunotherapy, SD-101, if developed, approved and commercialized will compete with a range of therapies being used or studied to treat blood cancers and solid tumor malignancies, including:

- Chemotherapeutic agents;
- Immuno-oncology agents, including immune checkpoint inhibitors such as anti-CTLA4 and anti-PD1 antibodies, immune stimulation therapies including agonists of TLR and other innate immune recognition receptors; and
- Targeted therapies, such as BRAF inhibitors and MEK inhibitors.

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

We are in direct competition with a number of other companies developing TLR agonist as well as other mechanisms of action that are focused on stimulating the immune response. These companies include Aduro Biotech, Inc., Idera Pharmaceuticals, Inc., Immune Design Corp. and Checkmate Pharmaceuticals, Inc.

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.

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 with 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

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose extensive requirements upon the clinical development, pre-market approval, manufacture, labeling, marketing, promotion, pricing, import, export, storage and distribution of biopharmaceuticals. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of drugs and biologics. Failure to comply with applicable FDA or foreign regulatory agency requirements may result in warning letters, fines, civil or criminal penalties, additional reporting obligations and/or agency oversight, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations and biologics additionally under the Public Health Service Act. The process required by the FDA before biopharmaceuticals may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive pre-clinical laboratory tests and pre-clinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials to demonstrate the safety, purity and potency of the product for the indication for use;
- a determination by the FDA within sixty days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with the FDA's current good manufacturing practices regulations for pharmaceuticals, or cGMPs; and
- FDA review and approval of a BLA prior to any commercial marketing or sale of the product in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

The results of pre-clinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the thirty-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information.

Clinical Trials. For purposes of BLA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- *Phase 1.* Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically in healthy humans, but in some cases in patients.
- *Phase 2.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3.* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- *Phase 4.* The FDA may approve a BLA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the product after approval under a post-marketing commitment or post-marketing requirement. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved a product. Post-approval trials are typically referred to as Phase 4 clinical trials.

The results of biologic development, pre-clinical studies and clinical trials are submitted to the FDA as part of a BLA. Applications also must contain extensive manufacturing and control information. Applications must be accompanied by a significant user fee. Once the submission has been accepted for filing, the FDA's goal is to review applications within twelve months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, eight months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA will typically conduct a pre-approval inspection of the manufacturer to ensure that the product can be reliably produced in compliance with cGMPs and will typically inspect certain clinical trial sites for compliance with good clinical practice, or GCP. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an application by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Approval may occur with boxed warnings on product labeling or Risk Evaluation and Mitigation Strategies, or REMS, which limit the labeling, distribution or promotion of a product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review, payment of product and manufacturing establishment fees and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action, additional reporting requirements and/or oversight by the agency, import alert or possible civil penalties. The FDA may also require us to recall a product from distribution or withdraw approval for that product.

The FDA closely regulates the post-approval marketing and promotion of pharmaceuticals, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet, including certain social media activities. Products may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental application, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential administrative, civil and criminal penalties, as well as damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs, additional reporting requirements and/or oversight by the agency, and imprisonment, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results.

Physicians may, in their independent medical judgment, prescribe legally available pharmaceuticals for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Additionally, a significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, or PDMA, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If our promotional activities, including any promotional activities that a contracted sales force may perform on our behalf, fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require corrective advertising or a recall or institute fines or civil fines, additional reporting requirements and/or oversight or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

Outside the United States, the ability of our partners and us to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country and region to region.

Healthcare Fraud and Abuse Laws. As a pharmaceutical company, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. These laws are applicable to manufacturers of products regulated by the FDA, such as us, and pharmacies, hospitals, physicians and other potential purchasers of such products.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is defined as any remuneration, direct or indirect, overt or covert, in cash or in kind, and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute may have been violated, and enforcement will depend on the relevant facts and circumstances. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to state that a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or to have offered improper inducements to federal health care program beneficiaries to select a particular provider or supplier. The federal Anti-Kickback Statute is broad, and despite a series of narrow statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. In addition, where such activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our activities with physician customers, pharmacies, and patients, as well as our activities pursuant to partnerships with other companies and pursuant to contracts with contract research organizations, could be subject to challenge under one or more of such laws.

The federal criminal and civil false claims laws, including the False Claims Act, which prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. In addition, the ACA specified that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The federal False Claims Act has been the basis for numerous enforcement actions and settlements by pharmaceutical and other healthcare companies in connection with various alleged financial relationships with customers. In addition, a number of pharmaceutical manufacturers have reached substantial financial settlements in connection with allegedly causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses. Certain marketing practices, including off-label promotion, may also violate false claims laws, as might violations of the federal physician self-referral laws, such as the Stark laws, which prohibit a physician from making a referral to certain designated health services with which the physician or the physician’s family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to the prohibited referral. The “qui tam” provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted similar fraud and abuse statutes or regulations, including, without limitation, false claims laws analogous to the False Claims Act that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Separately, there are a number of other fraud and abuse laws that pharmaceutical manufacturers must be mindful of, particularly after a product candidate has been approved for marketing in the United States. For example, a federal criminal law enacted as part of, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. There are also federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Healthcare Privacy and Security Laws. We may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which established uniform standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” — independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. State laws also govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

“Sunshine” and Marketing Disclosure Laws. There are an increasing number of federal and state “sunshine” laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. In addition, a similar federal requirement, known as the Physician Payments Sunshine Act, requires manufacturers, including pharmaceutical manufacturers, to track and report annually to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government discloses the reported information on a publicly available website. Certain states, such as Massachusetts, also make the reported information publicly available. In addition, there are state and local laws that require pharmaceutical representatives to be licensed and comply with codes of conduct, transparency reporting, and other obligations. These laws may adversely affect our sales, marketing, and other activities with respect to our products in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Government Price Reporting. For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including “covered entities” purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the “additional rebate”, a complex calculation which is based, in part, on the rate at which a branded drug price increases over time more than the rate of inflation (based on the CPI-U). This comparison is based on the baseline pricing data for the first full quarter of sales associated with a branded drug’s NDA, and baseline data cannot generally be reset, even on transfer of the NDA to another manufacturer. This “additional rebate” calculation can, in some cases where price increase have been relatively high versus the first quarter of sales of the NDA, result in Medicaid rebates up to 100 percent of a drug’s “average manufacturer price” and 340B prices of one penny.

In General. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities in the United States could be subject to challenge under one or more of such laws. Moreover, state governmental agencies may propose or enact laws and regulations that extend or contradict federal requirements. If we or our operations are found to be in violation of any of the state or federal laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in U.S. federal or state healthcare programs, additional reporting requirements and/or oversight, if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from participation in federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, sunshine, government price reporting, and fraud laws may prove costly.

Impact of Healthcare Reform and Recent Public Scrutiny of Specialty Drug Pricing on Coverage, Reimbursement, and Pricing. In the United States and other potentially significant markets for our products, - federal and state authorities as well as third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average net selling prices. Further, there is increased scrutiny of prescription drug pricing practices by federal and state lawmakers and enforcement authorities. In addition, there is an emphasis on managed healthcare in the United States, which will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs (including a number of proposals pertaining to prescription drugs, specifically), improving quality and/or expanding access. For example, in Massachusetts, the MassHealth program has requested permission from the federal government to use commercial tools, such as a closed formulary, to negotiate more favorable rebate agreements from drug manufacturers. There also has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in California, effective January 1, 2019, drug companies must notify insurers and government regulators of certain price increases and provide an explanation of the reasons for such increases.

In the United States, the pharmaceutical industry has already been significantly affected by major legislative initiatives, including, for example, the ACA. The ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". We continue to evaluate the effect that the ACA and additional actions by Congress to possibly repeal and replace it has on our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding. In the future, there will likely continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

MANUFACTURING

We rely on our facility in Düsseldorf, Germany and third parties to perform the multiple processes involved in manufacturing our product candidates, including the manufacturing of TLR agonists, antigens, and the formulation, fill and finish of the resultant products. 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. In order to successfully manufacture and commercialize HEPLISAV-B, we have secured long term supply agreements with the key third party suppliers and vendors for supply of product for commercialization. To date, we have manufactured only small quantities of TLR agonists ourselves for development purposes. We currently manufacture the HBsAg for HEPLISAV-B at our Dynavax GmbH facility and are in the process of reinitiating our commercial production capabilities in that facility, which is essential to our continuing ability to supply commercial product once our existing inventory of HEPLISAV-B is sold.

RESEARCH AND DEVELOPMENT

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were \$65.0 million, \$84.5 million and \$86.9 million for the years ended December 31, 2017, 2016 and 2015, 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 results of operations in the future.

EMPLOYEES

As of December 31, 2017, we had 170 full-time employees, including 111 employees in our headquarters in Berkeley, California and 59 employees in our office and manufacturing facility in Düsseldorf, Germany. As of February 28, 2018, we had 192 employees, including 121 full-time employees in Berkeley, California and 71 employees in Düsseldorf, Germany.

THE COMPANY AND BACKGROUND

Dynavax Technologies Corporation was 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 were reincorporated in Delaware in November 2000 and 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.

ITEM 1A. RISK FACTORS

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

Risks Related to our Business and Capital Requirements

We have launched HEPLISAV-B in the United States and we have personnel experienced with marketing drug products, but Dynavax has not previously commercialized a product. While we have recently established full commercial capabilities, given that this is Dynavax's first marketed product, there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.

We have established sales, marketing and distribution capabilities and commercialized HEPLISAV-B in the U.S. Successful commercialization of HEPLISAV-B, will require significant resources and time and, while Dynavax personnel are experienced with respect to marketing of prescription drug products, because HEPLISAV-B is the company's first marketed product, there is a risk that we may not successfully commercialize HEPLISAV-B. In addition, successful commercialization of HEPLISAV-B will require that we negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and that we maintain those contractual relationships. There is a risk that we may not complete or maintain all of these important contracts and thus our commercialization may not be successful. Moreover, we expect that significant resources will need to be invested in order to successfully market, sell and distribute HEPLISAV-B for use with diabetes patients. The Centers for Disease Control and Prevention ("CDC") and the CDC's Advisory Committee on Immunization Practices ("ACIP") recommend that patients with diabetes, one of our targeted patient populations, receive hepatitis B vaccinations and while the potential number of recommended vaccine adult patients is larger, we are unable to predict how many of those may receive HEPLISAV-B.

In addition to the risk with building and maintaining our own commercial capabilities and with contracting, other factors that may inhibit our efforts to successfully commercialize HEPLISAV-B include:

- whether we are able to recruit and retain adequate numbers of effective sales and marketing personnel;
- whether we are able to access key health care providers to discuss HEPLISAV-B;
- whether we can compete successfully as a new entrant in established distribution channels for vaccine products; and
- whether we will maintain sufficient funding to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure.

If we are not successful, we may be required to collaborate or partner with a third party pharmaceutical or biotechnology company with existing products. To the extent we determine to rely on other pharmaceutical or biotechnology companies or third party contract organizations with established sales, marketing and distribution capabilities to market HEPLISAV-B, we will need to establish and maintain collaboration arrangements, and we may not be able to enter into these arrangements on acceptable terms or for a period of time that may be required to establish HEPLISAV-B in the market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or in building and maintaining the infrastructure to support commercial operations, we will have difficulty successfully commercializing HEPLISAV-B, which would adversely affect our business and financial condition. To the extent our commercialization of HEPLISAV-B is not successful and we must partner with and rely upon the efforts of 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 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 and the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV-B, where existing products are already marketed. In the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, and we have achieved coverage with most third party payors. However, there is a risk that some payors may limit coverage to specific products on an approved list, also known as a formulary, which might not

include HEPLISAV-B. Thus, there can be no assurance that HEPLISAV-B will achieve and sustain stable pricing and favorable reimbursement. Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market's acceptance of a price for HEPLISAV-B sufficient to achieve profitability, and future acceptance of such pricing.

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 future products to compete effectively with existing 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 such unavailability could harm our future prospects and reduce our stock price.

Also, there has been heightened governmental scrutiny recently in the U.S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In some cases, such legislation and regulations have been designed to encourage importation from other countries and bulk purchasing. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business.

We are dependent on the commercial success of HEPLISAV-B and the success of our development stage products including SD-101, which depend on regulatory approval. Failure to maintain or obtain regulatory approvals could require us to discontinue operations.

The remainder of our pipeline consists of early stage oncology product candidates, and early stage development is inherently risky. Even if we have early indications of success in clinical development, in order to be able to market our products in the U.S., we must obtain approval from 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 FDA marketing approval and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The FDA 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 or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or proposed post-marketing study, or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations ("CROs"); and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, we received Complete Response Letters from the FDA for HEPLISAV-B in 2013 and 2016 before obtaining approval in November 2017.

In February 2014, we announced our withdrawal of our Marketing Authorization Application ("MAA") for approval of HEPLISAV-B to the EMA, 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. Our ability to market HEPLISAV-B outside the United States, such as in Europe, is dependent upon our receiving regulatory approval, which can be costly and time consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and/or take other measures which will take time and require that we incur expense. In addition, there is the risk that we may not receive approval in one or more jurisdictions.

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.

We are subject to ongoing FDA post-marketing obligations concerning HEPLISAV-B, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with HEPLISAV-B.

Our HEPLISAV-B regulatory approval is subject to certain post-marketing obligations and commitments to the FDA. We must conduct an observational comparative study of HEPLISAV-B to another Hepatitis B vaccine to assess occurrence of acute myocardial infarction; must conduct an observational surveillance study to evaluate the incidence of new onset immune-mediated diseases, herpes zoster and anaphylaxis; and must establish a pregnancy registry to provide information on outcomes following pregnancy exposure to HEPLISAV-B. These studies will require significant effort and resources, and failure to timely conduct these studies to the satisfaction of FDA could result in withdrawal of our BLA approval. The results of post-marketing studies may also result in additional warnings or precautions for the HEPLISAV-B label or expose additional safety concerns that may result in product liability and withdrawal of the product from the market, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for HEPLISAV-B are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, GCPs, ICH guidelines, and GLPs. If we are not able to meet and maintain regulatory compliance, we may lose marketing approval and be required to withdraw our product. As noted in the preceding paragraph, withdrawal would have a material adverse effect on our business.

We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We have not generated any revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net losses for the years ended December 31, 2017 and 2016 were \$95.2 million and \$112.4 million, respectively. As of December 31, 2017, we had an accumulated deficit of \$907.3 million.

With the approval of HEPLISAV-B and our investment in the launch and commercialization of this product in the U.S. in addition to our investment in our oncology product candidates, we expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. Our expenses will also increase substantially as we establish and maintain commercial infrastructure while continuing to invest in the clinical development of our oncology pipeline, reinitiate and invest in manufacturing and supply chain commitments to maintain commercial supply of HEPLISAV-B and continue to hire commercial, clinical, manufacturing and operational personnel in order to build our business. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine and pharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

If we are unable to achieve and sustain profitability, we will need to continue to raise funds through strategic alliance and licensing arrangements or the capital markets, including debt or equity or other structured finance mechanisms, in order to sustain our business and operations. As a result of those activities, the market value of our common stock may be negatively impacted and be volatile. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increases fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations and continue development of our product candidates.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in (a) commercialization of HEPLISAV-B, (b) clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and (c) discovery research and development. Until we can generate a sufficient amount of revenue, if any, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

The FDA may require more clinical trials for our development stage product candidates 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 involve combinations with other agents, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA requirements can be expensive and time consuming.

We are currently undertaking clinical trials of SD-101 and DV281, including combination studies with other oncology agents, and expect to commence clinical trials for other product candidates in our immuno-oncology pipeline in the future. Our strategy with respect to development of SD-101 and DV281 involves combination studies with other oncology agents. While we believe that this combination agent approach increases the potential for success, these clinical trials are dependent on continuing access to the other oncology agents, and for combination studies that are pursuant to a collaboration they are contingent on agreement with our combination agent study partners regarding the use of the other agents, concurrence on a protocol and supply of clinical materials. Most of our combination agent study partners, such as Merck & Co. (“Merck”), are significantly larger than we are and are conducting various other combination studies with other immuno-oncology agents and collaborators. We are not certain these clinical trials will be successful, or that even if successful we would be able to reach agreement to conduct larger, more extensive clinical trials required to achieve regulatory approval for a combination product candidate regimen. In addition, results from smaller, earlier stage clinical studies may not be representative of larger, controlled clinical trials that would be required in order to obtain regulatory approval of a product candidate or a combination of product candidates.

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 (“IRB”) or 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 CROs to conduct a clinical study in accordance with GCP standards and other applicable regulatory requirements 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 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.

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 GMP 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 with respect to our product candidates and those of our partners in combination agent studies:

- 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;
- a 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 a 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;
- a product candidate or combination study may appear to be no more effective than current therapies;
- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a 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;
- the inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue a 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;
- the 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
- the inability to retain participants who have initiated a clinical trial but may 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 patient populations, which often occur in later-stage clinical trials, or less favorable clinical outcomes. Moreover, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals.

Third party organizations such as 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 a 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, SD-101 and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue our operations.

Most of our programs, including HEPLISAV-B and SD-101, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue or modify many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. 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 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 oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. With respect to HEPLISAV-B, while we have reinitiated manufacturing and have a substantial quantity of available product, we are intending to switch to a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on timely approval of our pre-filled syringe by the FDA.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including HEPLISAV-B, SD-101, and DV281, certain antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. In connection with our restructuring in January 2017, we elected to retain, but furlough, much of the workforce in Düsseldorf supporting the manufacture of rHBsAg for HEPLISAV-B and utilize the existing stockpiled inventory of HEPLISAV-B to meet expected initial demand if the product was approved. Although we have sufficient inventory of HEPLISAV-B to launch the product and we have brought back staff at our facility in Düsseldorf that had been furloughed, hired additional staff where needed and reinstated manufacturing, there can be no assurance that we can successfully manufacture sufficient additional quantities in compliance with GMP in order to meet market demand. In addition, we have filed a BLA supplement with the FDA to manufacture and sell a pre-filled syringe presentation of HEPLISAV-B. Our ability to meet market demand in the future will be dependent upon timely FDA review and approval of the application.

We have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 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 suppliers for 1018 and SD-101, 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 product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

In countries outside of the U.S., 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 or disrupt the commercialization of HEPLISAV-B or our other product candidates and could result in significant expense.

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

With respect to HEPLISAV-B and our other product candidates in development, we and our third party manufacturers and suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and 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, third party manufacturers and suppliers and any 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 the FDA's inspections, it 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.

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.

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 approval and commercialization.

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 seek to 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 costs as well as burdens on our personnel resources in addition to potential diversion of 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 withdrew our MAA for HEPLISAV-B in Europe in 2014. We may not be able to provide sufficient data or respond to other comments to our previously filed MAA sufficient to obtain regulatory approval 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, require labeling content that diminishes market uptake of our products or limits our marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, such as the FDA approval of HEPLISAV-B in November 2017, 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 HEPLISAV-B and any of our future 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;
- 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 and the willingness of patients to pay out-of-pocket in the absence of sufficient reimbursement by third-party payors.

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.

A key part of our business strategy for products in development is to establish collaborative relationships to help fund development and commercialization 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 may need to establish collaborative relationships to obtain domestic and/or international sales, marketing and distribution capabilities for those product candidates. Failure to obtain a collaborative relationship for HEPLISAV-B in markets outside the U.S. requiring extensive sales efforts, may significantly impair the potential for this product and we may be required to raise additional capital. 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 as a result of 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 and marketing therapies to prevent or treat cancer and infectious and inflammatory diseases. For example, HEPLISAV-B competes in the U.S. with established hepatitis B vaccines marketed by Merck and GlaxoSmithKline plc (“GSK”) and if approved outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies.

Oncology is also a highly competitive market, with numerous biotechnology and pharmaceutical companies developing therapies for all of the targets we are pursuing. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier approval or patent protection or commercialization of their products. These competitive products may render our product candidates obsolete, change the standard of care against which our products much show safety and efficacy or limit our ability to generate revenues from our product candidates.

Existing and potential competitors may also compete with us for qualified commercial, scientific and management personnel, as well as for technology that would otherwise be advantageous to our business. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel in the near-term, particularly with respect to HEPLISAV-B commercialization. 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.

The term loan agreement we entered into in February, 2018 imposes significant operating and financial restrictions on us that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

In February, 2018, we entered into a term loan agreement under which we may borrow up to \$175 million. We have borrowed \$100 million under the agreement. Additional amounts may be borrowed only if we meet certain requirements. The agreement contains covenants that restrict our ability to take various actions, including, among other things, incur additional indebtedness, pay dividends or distributions or make certain investments, create or incur certain liens, transfer, sell, lease or dispose of assets, enter into transactions with affiliates, consummate a merger or sell or other dispose of assets. The agreement also requires us to comply with a daily minimum liquidity covenant and an annual revenue requirement based on the sales of HEPLISAV-B. The agreement specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default and the acceleration of our repayment obligation at a time when we may not have the cash to comply with that obligation, which could result in a seizure of most of our assets. The restrictions contained in the agreement could also limit our ability to meet

capital needs or otherwise restrict our activities and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

We rely on CROs and Clinical Sites and Investigators for 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 CROs, Clinical Sites and Investigators for 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 maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that clinical trials are conducted properly and 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.

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

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 successfully 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 and abuse, anticorruption, privacy, transparency and other 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. Our interactions with physicians and others in a position to prescribe or purchase our products are subject to a legal regime designed to prevent healthcare fraud and abuse and off-label promotion. We also are subject to laws pertaining to transparency of transfers of value to healthcare providers; privacy and data protection; compliance with industry voluntary compliance guidelines; and prohibiting the payment of bribes. Relevant U.S. laws include:

- the federal 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, including the civil False Claims Act, and civil monetary penalty law, 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;
- the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act (“PPACA”) which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created, among other things, new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the Foreign Corrupt Practices Act, which prohibits the payment of bribes to foreign government officials and requires that a company's books and records accurately reflect the company's transactions; and
- foreign and state law equivalents of each of the federal laws described above, 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 payor, including commercial insurers; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government.

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 federal civil False Claims Act 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), disgorgement, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws 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 cause us to 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. For example, the PPACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. Some of the provisions of PPACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may consider other legislation to repeal or replace elements of PPACA. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws and/or enforcement and other health care reform measures, 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. In addition, our continued growth to support commercialization may result in difficulties in managing our growth and expanding our operations successfully.

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.

As our operations expand, we expect that we will need to manage additional relationships with various vendors, partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to successfully commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to effectively manage our commercialization efforts, research efforts and clinical trials and hire, train and integrate additional regulatory, manufacturing, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company and achieving profitability.

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. While we have obtained product liability insurance coverage for HEPLISAV-B, there is a risk that 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.

Securities class action lawsuits against us are pending and purported stockholder derivative complaints 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and

our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

We use hazardous materials and controlled substances in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials and substances 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, and controlled substances. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials, substances, 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 and controlled substances. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials, or that controlled substances will be accidentally stored or used in violation of relevant federal, state and local requirements. In the event of an accident related to hazardous materials or a violation of requirements pertaining to controlled substances, 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, and laws and regulations pertaining to the storage and use of controlled substances.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

In addition, our systems are potentially vulnerable to data security breaches--whether by employees or others--that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

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 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.

GSK, a competitor of ours, is an exclusive licensee of broad patents covering methods of production of rHBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of rHBsAg in the U.S. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. We have had negotiations with GSK to obtain a license to its patents. However, there remains a risk that these negotiations may not result in a license, or that we may be required to agree to unfavorable terms. With our recent commercialization of HEPLISAV-B in the U.S., while these patents remain in force and until we obtain a license to its relevant patents, GSK or its licensor 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 connection with 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 for the term of such patents or are otherwise effectively maintained as trade secrets. For example, the TLR agonist contained in our HEPLISAV-B product has patent protection scheduled to expire in June 2018, and while we have applied for a patent term extension which could be up to a maximum of five years, there can be no assurance of the period of protection if and until such extension is granted. 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 BLA filing and communications, from the FDA or other regulatory agencies;
- our ability to receive timely regulatory approval for our product candidates;
- 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;
- the success or failure of clinical trials involving our immuno-oncology product candidates and the product candidates of third party collaborators in combination studies;
- 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; 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 and shareholder derivative 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 litigation, resulting from the decline in our common stock following the disclosure in November 2016 of the FDA's 2016 CRL related to HEPLISAV-B. We may in the future be the target of additional such litigation. Securities and shareholder derivative 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;
- 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 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, 2017 we had 61,532,812 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.

Under our universal shelf registration statement filed by us in August 2017, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our 2017 At Market Sales Agreement with Cowen under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of \$150,000,000. As of December 31, 2017, we have \$132.8 million remaining under this agreement. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2017, we lease approximately 40,700 square feet of laboratory and office space in Berkeley, California under agreements expiring in December 2025. 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, Dynavax receives 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, lead plaintiff filed his consolidated class action complaint (the “consolidated complaint”), which named a former director of the Company as a defendant in addition to the Company and the former executive officers identified in the two prior complaints (collectively, the “defendants”). The consolidated complaint alleged that between April 26, 2012 and June 10, 2013, the Company and certain of its executive officers and directors violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, in connection with statements related to the Company’s product, HEPLISAV-B, an investigational adult hepatitis B vaccine. The consolidated complaint sought unspecified damages, interest, attorneys’ fees, and other costs.

On September 7, 2016, the parties signed the Stipulation of Settlement, which provides for a payment of \$4.5 million by the defendants, of which the Company is responsible for \$4.1 million, and results in the dismissal and release of all claims against the defendants in connection with the securities class action, upon final court approval. The settlement was paid for by the Company's insurance carriers. On February 6, 2017, the Court approved the settlement and entered a Final Order and Judgment dismissing the case with prejudice.

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 current and former executive officers and 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 complaints allege 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. Plaintiffs are seeking unspecified monetary damages, including restitution from defendants, 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*. On May 8, 2015, the parties filed a stipulation to keep the state derivative case stayed until a final resolution in the *In re Dynavax Technologies Securities Litigation*. On May 15, 2015, the parties also stipulated to keep the federal derivative case stayed until a final resolution in the *In re Dynavax Technologies Securities Litigation*. The parties entered into a stipulation of settlement which provides that the Company will enter into certain corporate governance reforms, that the Company shall cause to be paid an attorneys' fee of \$925,000 to plaintiffs' counsel, and for dismissal of all claims against defendants in both the state and federal derivative actions. On August 21, 2017, the state court entered an order preliminarily approving the settlement and setting a final approval hearing date of October 17, 2017. On October 17, 2017, the state court entered the final approval order and dismissed the state court action. On October 20, 2017, the parties to the federal derivative action submitted a stipulation to the federal court to dismiss with prejudice the federal derivative action in light of the settlement. On October 24, 2017, the federal court granted the stipulation and dismissed the federal derivative action with prejudice.

On November 18, 2016, two substantially similar securities class action complaints were filed in the U.S. District Court for the Northern District of California against the Company and two of its executive officers, in *Sootjens v. Dynavax Technologies Corporation et al.*, ("*Sootjens*") and *Shumake v. Dynavax Technologies Corporation et al.*, ("*Shumake*"). The *Sootjens* complaint alleges that between March 10, 2014 and November 11, 2016, the Company and certain of its executive officers violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, in connection with statements related to HEPLISAV-B. The *Shumake* complaint alleges violations of the same statutes related to the same subject, but between January 7, 2016 and November 11, 2016. The plaintiffs in both actions are seeking an unspecified amount of damages and attorneys' fees and costs. On January 17, 2017, these two actions 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 January 31, 2017, the court appointed lead plaintiff and lead counsel. Lead plaintiff filed a consolidated amended complaint on March 17, 2017. Defendants' filed a motion to dismiss the consolidated amended complaint on May 1, 2017. On September 12, 2017, the District Court granted Defendants' motion to dismiss, but gave lead plaintiff an opportunity to amend his complaint. On October 3, 2017, plaintiff filed a Second Amended Complaint. Defendants filed a motion to dismiss the Second Amended Complaint on November 3, 2017. A hearing on Defendants' motion to dismiss was set for January 23, 2018, but the hearing was vacated by the Court on January 18, 2018. In vacating the hearing, the Court indicated that the hearing would be reset if the Court found oral argument necessary. To date, no hearing has been set on Defendants' motion to dismiss.

On January 18, 2017, the Company was made aware of a derivative complaint that a purported stockholder of the Company intended to file in the Superior Court of California for the County of Alameda against certain of the Company's current executive officers and directors (the "*McDonald* Complaint"). The *McDonald* Complaint was apparently filed on February 16, 2017, although the Company was not provided a copy of it until March 15, 2017. Additionally, on January 19, 2017, another purported stockholder of the Company filed a separate derivative complaint in the Superior Court of California for the County of Alameda against the same officers and directors who were named in the *McDonald* Complaint (the "*Shumake* Complaint"). Both complaints generally allege that the defendants caused or allowed the Company to issue materially misleading statements and/or omit material information regarding HEPLISAV-B and the clinical trial related thereto and otherwise mismanaged the clinical trial related to HEPLISAV-B. The complaints seek unspecified monetary damages, including restitution from defendants, corporate governance changes, attorneys' fees and costs, and other relief. Defendants were never served with the *Shumake* Complaint. On June 23, 2017, the plaintiff voluntarily dismissed the *Shumake* Complaint without prejudice. Defendants filed a demurrer in the *McDonald* case seeking to dismiss the lawsuit on

June 19, 2017. On July 26, 2017, pursuant to a stipulation between the parties, the state court stayed the *McDonald* case pending the final resolution of the 2016 securities class action, *In re Dynavax Technologies Securities Litigation*.

On December 1, 2017, the purported stockholder of the Company who filed, and then later voluntarily dismissed, the state court *Shumake* Complaint, filed a substantially similar purported stockholder derivative complaint in the U.S. District Court for the Northern District of California (the “Federal *Shumake* Action”). On February 13, 2018, pursuant to a stipulation between the parties, the District Court stayed the Federal *Shumake* Action pending the final resolution of the 2016 securities class action, *In re Dynavax Technologies Securities Litigation*.

The Company believes that it has meritorious defenses and intends to defend these lawsuits vigorously. However, the lawsuits are subject to inherent uncertainties, the actual costs may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies with respect to these lawsuits, but coverage could be denied or prove to be insufficient.

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 Price	
	High	Low
2017		
First Quarter	\$ 7.45	\$ 3.70
Second Quarter	\$ 10.70	\$ 5.00
Third Quarter	\$ 21.85	\$ 8.15
Fourth Quarter	\$ 24.45	\$ 16.85
2016		
First Quarter	\$ 29.86	\$ 15.52
Second Quarter	\$ 23.62	\$ 12.84
Third Quarter	\$ 17.50	\$ 10.11
Fourth Quarter	\$ 13.23	\$ 3.20

As of March 1, 2018, there were approximately 50 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 16,300 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.

In February 2018, we entered into a \$175.0 million term loan agreement ("Loan Agreement") with CRG Servicing LLC. The Loan Agreement restricts our ability to pay any dividend.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

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, 2017, 2016 and 2015 and the Consolidated Balance Sheets Data as of December 31, 2017 and 2016 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, 2014 and 2013 and the Consolidated Balance Sheets Data as of December 31, 2015, 2014 and 2013 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,				
	2017	2016	2015	2014	2013
(In thousands, except per share data)					
Consolidated Statements of Operations Data:					
Total revenues	\$ 327	\$ 11,043	\$ 4,050	\$ 11,032	\$ 11,251
Operating expenses:					
Amortization of intangible assets	1,194	-	-	-	-
Research and development	64,988	84,493	86,943	84,580	50,870
Selling, general and administrative	27,367	37,257	22,180	17,377	25,943
Restructuring	2,783	-	-	-	-
Unoccupied facility expense	-	-	-	386	926
Total operating expenses	96,332	121,750	109,123	102,343	77,739
Loss from operations	(96,005)	(110,707)	(105,073)	(91,311)	(66,488)
Other income (expense):					
Interest income	1,337	755	205	191	116
Interest expense	-	-	(572)	(35)	-
Other (expense) income, net	(486)	(2,492)	317	433	(348)
Loss on extinguishment of debt ⁽¹⁾	-	-	(1,671)	-	-
Net loss	(95,154)	(112,444)	(106,794)	(90,722)	(66,720)
Net loss attributable to Dynavax	(95,154)	(112,444)	(106,794)	(90,722)	(66,720)
Preferred stock deemed dividend ⁽²⁾	-	-	-	-	(8,469)
Net loss allocable to Dynavax common stockholders	\$ (95,154)	\$ (112,444)	\$ (106,794)	\$ (90,722)	\$ (75,189)
Basic and diluted net loss per share allocable to Dynavax common stockholders	\$ (1.81)	\$ (2.92)	\$ (3.25)	\$ (3.45)	\$ (3.83)
Shares used to compute basic and diluted net loss per share allocable to Dynavax common stockholders	52,613	38,506	32,881	26,289	19,628

- (1) In September 2015, we repaid all outstanding amounts under a loan agreement. We recognized the repayment to be a substantial modification to the debt instrument and applied debt extinguishment accounting to record a one-time loss on extinguishment of debt in the amount of \$1.7 million.
- (2) 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 was 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,				
	2017	2016	2015	2014	2013
(In thousands)					
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	\$ 191,854	\$ 81,415	\$ 196,125	\$ 122,652	\$ 189,376
Working capital	179,430	69,563	171,161	107,158	176,186
Total assets	218,785	109,680	216,633	138,290	204,622
Long-term debt ⁽¹⁾	-	-	-	9,559	-
Accumulated deficit	(907,325)	(812,171)	(699,727)	(592,933)	(502,211)
Total stockholders' equity	199,549	89,201	187,079	100,482	186,294

- (1) All outstanding amounts under a loan agreement were repaid in cash September 2015.

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

We are a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our first commercial product, HEPLISAV-B™ (Hepatitis B Vaccine (Recombinant), Adjuvanted), was approved by the United States Food and Drug Administration ("FDA") in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology products are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1 safety study.

Our lead investigational immuno-oncology product is SD-101. SD-101 is currently being evaluated in a Phase 2 clinical study in melanoma and in head and neck squamous cell carcinoma. We are conducting a research and clinical program intended to assess potential efficacy of SD-101 in a range of tumors and in combination with a range of treatments, including checkpoint inhibitors and other therapies, and expect additional studies will be initiated during 2018.

Our second immuno-oncology product candidate is DV281, a novel investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases as an inhaled aerosol. In October 2017, we announced initiation of dosing in a Phase 1b study of inhaled DV281, in combination with anti-PD-1 therapy, in patients with non-small cell lung cancer.

In addition to the research programs we are conducting and product candidates we are developing, we discovered and licensed to AstraZeneca AB ("AstraZeneca") an inhaled TLR agonist, AZD1419, which is being developed by AstraZeneca for the treatment of asthma pursuant to a collaboration and license agreement. AstraZeneca initiated a Phase 2a trial in 2016.

Our revenues have historically consisted of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to successfully market HEPLISAV-B and our product candidates, if they are approved. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of \$907.3 million as of December 31, 2017. 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 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. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. Selling, general and administrative expenses include outside services such as accounting, consulting, business development, commercial, investor relations, insurance services and legal costs.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in (a) commercialization of HEPLISAV-B, (b) clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and (c) discovery research and development. Until we can generate a sufficient amount of revenue, if any, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, 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 accounting policies reflect the more critical and significant judgments and estimates used in the preparation of our consolidated financial statements.

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 contracts with third parties 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.

Our accrual for clinical trials is 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 estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time.

Stock-Based Compensation

Stock-based compensation expense for restricted stock units and stock options is estimated at the grant date based on the award's estimated fair value-based measurement and is recognized on a straight-line basis over the award's requisite service period, assuming estimated forfeiture rates. Fair value of restricted stock units is determined at the date of grant using our closing stock price. 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 subjective variables. 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 assumptions which determine the fair value-based measurement of stock options. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, 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.

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 period of revision.

Inventories

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. Only once regulatory approval is obtained, would we begin capitalization of these inventory related costs.

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time, we began to capitalize inventory costs associated with HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B, that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. At December 31, 2017, we had approximately 250,000 vials of pre-commercialization inventory of HEPLISAV-B which we expect to sell over at least the next nine months. We periodically analyze our inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements. Expired inventory will be disposed of and the related costs written off.

Accounting for Income Taxes

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Tax law and rate changes are reflected in income in the period such changes are enacted. We include interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

On December 22, 2017, President Trump signed U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which became effective January 1, 2018. The Tax Act significantly changes the fundamentals of U.S. corporate income taxation by, among many other things, reducing the U.S. federal corporate income tax rate to 21%, converting to a territorial tax system, and creating various income inclusion and expense limitation provisions. We have performed a review of the Tax Act, and based on information available at December 31, 2017, recorded certain provisional amounts related to the revaluation of our deferred taxes and the realization of certain tax credit carryforwards. Due to insufficient guidance on certain aspects of the Tax Act, such as officer's compensation, as well as uncertainty around the GAAP treatment associated with many other parts of the Tax Act, such as the implementation of certain international provisions, we cannot be certain that all deferred tax assets and liabilities have been established for the future effects of the legislation. Therefore, the final accounting for these provisions is subject to change as further information becomes available and further analysis is complete. Additionally, given the uncertainty and complexity of these new international tax regimes, we are continuing to evaluate how these provisions will be accounted for under U.S. generally accepted accounting principles; therefore, we have not yet adopted an accounting policy for treating the effects of these provisions as either a component of income tax expense in the period the tax arises, or through adjusting our deferred tax assets and liabilities to account for the estimated future impact of the special international tax regimes.

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential adjustments and adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Significant judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and

includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

Based on our review, we concluded that it was more likely than not that we would not be able to realize the benefit of our domestic and foreign deferred tax assets in the future. This conclusion was based on historical and projected operating performance, as well as our expectation that our operations will not generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets within the statutory carryover periods. Therefore, we have maintained a full valuation allowance on our deferred tax assets as of December 31, 2017 and 2016.

We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

Recent Accounting Pronouncements

Accounting Standards Update ("ASU") 2014-09

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which introduced Accounting Standards Codification ("ASC") 606, *Revenue Recognition, Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods), with early application permitted. The FASB issued supplemental adoption guidance and clarification to ASU 2014-09 in March 2016, April 2016 and May 2016 within ASU 2016-08 "Revenue From Contracts With Customers: Principal vs. Agent Considerations," ASU 2016-10 "Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing," and ASU 2016-12 "Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients," respectively. We will adopt ASU 2014-09 on January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of that date. We have completed our analysis on the adoption of ASU 2014-09 of our revenues, identifying that there are no remaining performance obligations as of the adoption date. Based on this assessment, adopting this standard will not have a material impact on our consolidated financial statements and we do not expect to record any adjustment to accumulated deficit.

Results of Operations

Revenues

Revenues have historically consisted of amounts earned from collaborations, grants and services and license fees. 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 (in thousands, except for percentages):

Revenues:	Year Ended December 31,			Increase (Decrease) from 2016 to 2017		Increase (Decrease) from 2015 to 2016	
	2017	2016	2015	\$	%	\$	%
Collaboration revenue	\$ -	\$ 9,778	\$ 2,765	\$ (9,778)	(100)%	\$ 7,013	254%
Grant revenue	295	381	683	(86)	(23)%	(302)	(44)%
Service and license revenue	32	884	602	(852)	(96)%	282	47%
Total revenues	<u>\$ 327</u>	<u>\$ 11,043</u>	<u>\$ 4,050</u>	<u>\$ (10,716)</u>	<u>(97)%</u>	<u>\$ 6,993</u>	<u>173%</u>

2017 versus 2016

No collaboration revenue was recognized in 2017 as all performance obligations under the AstraZeneca agreement were completed in 2016. Service and license revenue decreased in 2017 as no manufacturing services were performed on behalf of third parties in 2017. We are eligible to receive future milestone payments and sales-based royalties from AstraZeneca. For the year ended December 31, 2017, no milestones were achieved and there were no royalties from AstraZeneca.

2016 versus 2015

Collaboration revenue increased due to recognition of \$7.2 million under the research collaboration and license agreement with AstraZeneca for the initiation of a Phase 2a trial by AstraZeneca in 2016. Grant revenue decreased due to expiration of various contracts with the National Institute of Health in 2015. Service and license revenue increased due to revenue received from manufacturing services performed on behalf of a third party.

HEPLISAV-B was approved by the FDA on November 9, 2017 and commercial shipments began in the first quarter of 2018.

Amortization of Intangible Assets

Amortization of intangible assets of \$1.2 million for the year ended December 31, 2017 consists of amortization of the intangible asset recorded as a result of a regulatory milestone payment due to Coley Pharmaceutical Group, Inc. upon FDA approval of HEPLISAV-B in November 2017. At December 31, 2017, this asset has an estimated remaining useful life of two months and the remaining amount of the intangible assets will be fully amortized during the first quarter of 2018.

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 consist of costs associated with clinical development, preclinical discovery and development, regulatory filings and research, including fees and expenses incurred by contract research organizations, clinical study sites, and other service providers and costs of manufacturing product candidates prior to approval. For the years ended December 31, 2017, 2016 and 2015, approximately 33%, 67% and 80%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to HEPLISAV-B. Prior to FDA approval, we recorded as research and development expense costs of acquiring, developing and manufacturing HEPLISAV-B.

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

Research and Development:	Year Ended December 31,			Increase (Decrease) from 2016 to 2017		Increase (Decrease) from 2015 to 2016	
	2017	2016	2015	\$	%	\$	%
	Compensation and related personnel costs	\$ 28,577	\$ 34,333	\$ 30,183	\$ (5,756)	(17)%	\$ 4,150
Outside services	20,112	32,540	45,495	(12,428)	(38)%	(12,955)	(28)%
Facility costs	8,472	10,878	7,142	(2,406)	(22)%	3,736	52%
Non-cash stock-based compensation	7,827	6,742	4,123	1,085	16%	2,619	64%
Total research and development	<u>\$ 64,988</u>	<u>\$ 84,493</u>	<u>\$ 86,943</u>	<u>\$ (19,505)</u>	<u>(23)%</u>	<u>\$ (2,450)</u>	<u>(3)%</u>

2017 versus 2016

Compensation and related personnel costs decreased due to implementation of organizational restructuring and cost reduction plans in January 2017. Outside services expense decreased primarily due to a reduction of costs related to HEPLISAV-B clinical trials and manufacturing activities partially offset by increased costs relating to seeking regulatory approval for HEPLISAV-B and the ongoing development of SD-101, DV281 and earlier stage oncology programs. Non-cash stock-based compensation increased due to recognition of expense related to share-based awards granted to employees in 2017 and prior years. Facility costs, which includes an overhead allocation primarily comprised of occupancy and related expenses, decreased due to overall lower facility and related costs and a decrease in headcount.

2016 versus 2015

Compensation and related personnel costs and non-cash stock-based compensation increased due to an overall increase in employee headcount in preparation for the anticipated commercialization of HEPLISAV-B and recognition of expense related to share-based awards granted to employees in 2015 and 2016. Outside services expense decreased primarily due to lower activity related to completion in October 2015 of HBV-23, a large Phase 3 study of HEPLISAV-B. The decrease in costs relating to HBV-23 was partially offset by increased costs relating to seeking regulatory approval, preparation for commercialization of HEPLISAV-B and the ongoing development of SD-101 and earlier stage oncology programs. Facility costs, which includes an overhead allocation primarily comprised of occupancy and related expenses, increased primarily due to an increased allocation of facilities expenses resulting from an increase in R&D headcount.

We expect research and development spending to increase in 2018 in connection with the discovery, development and manufacturing of our product candidates, particularly SD-101 and DV281, and the pre-filled syringe presentation of HEPLISAV-B.

Selling, General and Administrative

Selling, general and administrative expense consists primarily of compensation and related costs for our commercial and medical education professionals and commercial support personnel and personnel in executive and other administrative functions; costs for outside services such as accounting, commercial development, consulting, business development, investor relations and insurance; 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 selling, general and administrative expenses (in thousands, except for percentages):

Selling, General and Administrative:	Year Ended December 31,			Increase (Decrease) from 2016 to 2017		Increase (Decrease) from 2015 to 2016	
	2017	2016	2015	\$	%	\$	%
Compensation and related personnel costs	\$ 8,685	\$ 11,814	\$ 8,765	\$ (3,129)	(26)%	\$ 3,049	35%
Outside services	7,611	14,400	5,588	(6,789)	(47)%	8,812	158%
Legal costs	2,777	2,458	1,721	319	13%	737	43%
Facility costs	1,204	1,201	912	3	0%	289	32%
Non-cash stock-based compensation	7,090	7,384	5,194	(294)	(4)%	2,190	42%
Total selling, general and administrative	<u>\$ 27,367</u>	<u>\$ 37,257</u>	<u>\$ 22,180</u>	<u>\$ (9,890)</u>	<u>(27)%</u>	<u>\$ 15,077</u>	<u>68%</u>

2017 versus 2016

Compensation and related personnel costs and non-cash stock-based compensation decreased due to implementation of organizational restructuring and cost reduction plans in January 2017. Outside services decreased as 2016 included costs related to hiring of consultants for administrative and commercial development services for the anticipated commercial launch of HEPLISAV-B.

2016 versus 2015

Compensation and related personnel costs increased due to an overall increase in employee headcount in preparation for the anticipated commercial launch of HEPLISAV-B in the United States. Outside services increased due to expenses related to sourcing of a debt financing commitment and retention of consultants for administrative and commercial development services for the anticipated commercial launch of HEPLISAV-B. Non-cash stock-based compensation increased due to increased annual stock option grants in 2016 and a full year of expense related to 2015 annual option grants recognized in 2016.

We expect our selling, general and administrative expenses to increase in 2018 in support of HEPLISAV-B commercial activities and post-marketing studies, ongoing support for our other product candidates and increasing costs of operating as a public company.

Restructuring

In January 2017, we implemented organizational restructuring and cost reduction plans to align around our immuno-oncology business while allowing us to advance HEPLISAV-B through the FDA review and approval process. To achieve these cost reductions, we suspended manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B and reduced our global workforce by approximately 40 percent.

For the year ended December 31, 2017 we recorded charges of \$2.8 million related to severance, other termination benefits and outplacement services. As of December 31, 2017, we have paid the full amount of the restructuring charges.

Interest Income, Interest Expense, Other (Expense) Income, Net and Loss on Extinguishment of Debt

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense for the year ended December 31, 2015 includes interest expense related to a loan agreement entered into in December 2014. In September 2015, the debt was fully repaid. Other income (expense), net includes gains and losses on foreign currency transactions. In addition, other income (expense), net for the year ended December 31, 2016 includes expenses related to an unutilized note purchase agreement which was terminated in December 2016.

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

	Year Ended December 31,			Increase (Decrease) from 2016 to 2017		Increase (Decrease) from 2015 to 2016	
	2017	2016	2015	\$	%	\$	%
	Interest income	\$ 1,337	\$ 755	\$ 205	\$ 582	77%	\$ 550
Interest expense	\$ -	\$ -	\$ (572)	\$ -	-	\$ (572)	(100)%
Other (expense) income, net	\$ (486)	\$ (2,492)	\$ 317	\$ (2,006)	(80)%	\$ (2,809)	(886)%
Loss on extinguishment of debt	\$ -	\$ -	\$ (1,671)	\$ -	-	\$ 1,671	100%

2017 versus 2016

Interest income increased due to a higher average rate of return on our investments and a higher average investment balance. The change in other (expense) income, net is primarily due to foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar.

2016 versus 2015

Interest income increased due to a marketable security balance during the year containing higher yielding securities. Interest expense decreased due to repayment in September 2015 of the loan under the Loan Agreement. Other (expense) income, net decreased due to a \$1.0 million payment upon entering into and subsequent \$1.5 million payment related to termination of a note purchase agreement. In addition, other (expense) income, net increased by \$0.2 million due to a gain on foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar. In September 2015, we recognized a one-time loss on extinguishment of debt of \$1.7 million related to the early repayment of the outstanding balance under the terms of the loan agreement.

Other (expense) income, net includes expense of \$5.0 million related to the settlement of securities litigation and the tentative settlement of derivative complaints initiated in 2013. This expense was offset by \$5.0 million in other income as the settlements will be paid for by the Company's insurers. For more information about the Company's settlements, see Note 9, *Commitments and Contingencies*, in our Notes to Consolidated Financial Statements.

Liquidity and Capital Resources

As of December 31, 2017, we had \$191.9 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, government grants and revenues from collaboration agreements to fund our operations. Our funds are currently invested in short-term money market funds, U.S. Treasuries, U.S. Government agency securities and corporate debt securities. Certain of these investments

are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in (a) commercialization of HEPLISAV-B, (b) clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and (c) discovery research and development. We expect that cash used in operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results, working capital requirements and capital deployment decisions. Until we can generate a sufficient amount of revenue, if any, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

In February 2018, we entered into a \$175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. The Loan Agreement provides for a \$175.0 million term loan facility, \$100.0 million of which was borrowed at closing and, subject to the satisfaction of certain market capitalization and other borrowing conditions, up to an additional \$75.0 million at our option on or before July 17, 2019. The loans have a maturity date of December 31, 2023, unless earlier prepaid. The loans bear interest at a rate equal to 9.50% per annum.

During 2017, we received net cash proceeds of \$105.1 million resulting from sales of 16,837,976 shares of common stock under our At Market Sales Agreements with Cowen and Company, LLC (“ATM Agreements”). At December 31, 2017, an additional \$132.8 million of common stock remained available for sale under an ATM Agreement.

In August 2017, we completed an underwritten public offering of 5,750,000 shares of our common stock for net proceeds of approximately \$80.8 million, after deducting the underwriting discount and other estimated offering expenses payable by us.

2017 versus 2016

During the year ended December 31, 2017, we used \$77.5 million of cash for our operations primarily due to our net loss of \$95.2 million, of which \$18.9 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, amortization of intangible assets and accretion and amortization on marketable securities. During the year ended December 31, 2016, we used \$107.1 million of cash for our operations primarily due to a net loss of \$112.4 million, of which \$18.1 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, write-off of assets in progress and accretion and amortization on marketable securities. Cash used in our operations during 2017 decreased by \$29.5 million. Net cash used in operating activities is impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the year ended December 31, 2017, cash used in investing activities was \$108.7 million compared to \$86.2 million of cash provided by investing activities for the year ended December 31, 2016. Cash used in investing activities during the year ended December 31, 2017 included \$108.0 million of net purchases of marketable securities compared with \$94.0 million of net proceeds from maturities of marketable securities during 2016. Net cash used in the purchases of equipment decreased by \$7.1 million from 2016 to 2017 primarily due to upgrades made to our manufacturing facility during 2016.

During the year ended December 31, 2017 and 2016, cash provided by financing activities was \$187.8 million and \$0.5 million, respectively. During the year ended December 31, 2017, we received net cash proceeds of \$105.1 million from issuance of common stock under our ATM Agreements and \$80.8 million in net proceeds from issuance of our common stock from our August 2017 underwritten public offering. We received proceeds of \$1.9 million and \$0.5 million from exercises of options as well as employee purchases of our common stock under the 2014 Employee Stock Purchase Plan during the year ended December 31, 2017 and 2016, respectively.

2016 versus 2015

During the year ended December 31, 2016, we used \$107.1 million of cash for our operations primarily due to our net loss of \$112.4 million, of which \$18.1 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, write-off of assets in progress and accretion and amortization on marketable securities. By comparison, during the year ended December 31, 2015, we used \$92.6 million of cash for our operations primarily due to a net loss of \$106.8 million, of which \$13.3 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, loss on extinguishment of debt and accretion and amortization on marketable securities. Cash used in our operations during 2016 increased by \$14.5 million. Net cash used in operating activities is impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the year ended December 31, 2016, cash provided by investing activities was \$86.2 million compared to \$85.8 million of cash used in investing activities for the year ended December 31, 2015. Cash provided by investing activities during the year ended December 31, 2016 included \$94.0 million of net proceeds from maturities of marketable securities compared with \$78.8 million of net purchases of marketable securities during the same period in 2015. Net cash used in the purchases of equipment increased by \$0.8 million from 2015 to 2016 primarily due to upgrades made to our manufacturing facility. In December 2016, we terminated planning for a manufacturing facility, and incurred a one-time write-off of an amount equal to the carrying amount of the asset of approximately \$0.9 million.

During the year ended December 31, 2016 and 2015, cash provided by financing activities was \$0.5 million and \$174.0 million, respectively. During the year ended December 31, 2015, we received \$134.9 million in net proceeds from a public offering of common stock and \$49.0 million in net proceeds from issuance of common stock under our 2014 At Market Sales Agreement ("2014 ATM Agreement") which terminated in July 2015. These proceeds were partially offset by an \$11.0 million repayment of the loan in September 2015. We received proceeds of \$0.5 million and \$1.1 million from exercises of options and warrants as well as employee purchases of our common stock under the 2014 Employee Stock Purchase Plan during the year ended December 31, 2016 and 2015, respectively.

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2017 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2018	2019- 2020	2021-2022	2023 and Thereafter
Operating leases	\$ 19,223	\$ 2,356	\$ 5,180	\$ 5,092	\$ 6,595
Purchase commitments	5,387	5,387	-	-	-
Total contractual obligations	\$ 24,610	\$ 7,743	\$ 5,180	\$ 5,092	\$ 6,595

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in December 2025 and March 2023, respectively. In May 2017, we amended the Berkeley Lease to extend the term of the Berkeley Lease to expire in December 2025 and to terminate the lease of an adjacent building.

During 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, 2017 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, 2017 and 2016. 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.

During 2004, we also established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of 0.2 million Euros. The letter of credit remained outstanding through December 31, 2017 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, 2017 and 2016.

We enter into long-term purchase commitments with commercial manufacturers for the supply of HEPLISAV-B. To the extent these long-term commitments are non-cancelable, they are reflected in the above table.

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 also rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical material manufacturers. 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.

In conjunction with a financing arrangement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”) in November 2009, we agreed to make contingent cash payments to Holdings 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 cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. We have made no payments and have not recorded a liability as of December 31, 2017.

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 short-term money market funds, U.S. government agency securities, U.S. Treasuries and corporate debt 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 \$1.0 million or \$1.3 million, respectively.

Due to the short duration and 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 GmbH with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2017 was \$0.8 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2017, 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.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Dynavax Technologies Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation (the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 8, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002
San Francisco, California
March 8, 2018

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,584	\$ 24,289
Marketable securities available-for-sale	165,270	57,126
Accounts and other receivables	854	1,342
Inventories	312	-
Intangible assets, net	1,306	-
Prepaid expenses and other current assets	3,697	6,842
Total current assets	198,023	89,599
Property and equipment, net	16,619	17,174
Goodwill	2,244	1,971
Restricted cash	629	602
Other assets	1,270	334
Total assets	\$ 218,785	\$ 109,680
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,539	\$ 3,796
Accrued research and development	4,359	5,048
Accrued liabilities	9,695	11,192
Total current liabilities	18,593	20,036
Other long-term liabilities	643	443
Total liabilities	19,236	20,479
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized at December 31, 2017 and December 31, 2016; no shares issued and outstanding at December 31, 2017 and December 31, 2016	-	-
Common stock: \$0.001 par value; 139,000 and 69,500 shares authorized at December 31, 2017 and 2016, respectively; 61,533 and 38,599 shares issued and outstanding at December 31, 2017 and 2016, respectively	62	39
Additional paid-in capital	1,107,693	904,957
Accumulated other comprehensive loss	(881)	(3,624)
Accumulated deficit	(907,325)	(812,171)
Total stockholders' equity	199,549	89,201
Total liabilities and stockholders' equity	\$ 218,785	\$ 109,680

See accompanying notes.

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

	Year Ended December 31,		
	2017	2016	2015
Revenues:			
Collaboration revenue	\$ -	\$ 9,778	\$ 2,765
Grant revenue	295	381	683
Service and license revenue	32	884	602
Total revenues	<u>327</u>	<u>11,043</u>	<u>4,050</u>
Operating expenses:			
Amortization of intangible assets	1,194	-	-
Research and development	64,988	84,493	86,943
Selling, general and administrative	27,367	37,257	22,180
Restructuring	2,783	-	-
Total operating expenses	<u>96,332</u>	<u>121,750</u>	<u>109,123</u>
Loss from operations	(96,005)	(110,707)	(105,073)
Other income (expense):			
Interest income	1,337	755	205
Interest expense	-	-	(572)
Other (expense) income, net	(486)	(2,492)	317
Loss on extinguishment of debt	-	-	(1,671)
Net loss	<u>\$ (95,154)</u>	<u>\$ (112,444)</u>	<u>\$ (106,794)</u>
Basic and diluted net loss per share	<u>\$ (1.81)</u>	<u>\$ (2.92)</u>	<u>\$ (3.25)</u>
Weighted average shares used to compute basic and diluted net loss per share	<u>52,613</u>	<u>38,506</u>	<u>32,881</u>

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2017	2016	2015
Net loss	\$ (95,154)	\$ (112,444)	\$ (106,794)
Other comprehensive income (loss), net of tax:			
Unrealized (loss) gain on marketable securities available-for-sale	(83)	(8)	11
Cumulative foreign currency translation adjustments	2,826	(686)	(1,272)
Total other comprehensive income (loss)	<u>2,743</u>	<u>(694)</u>	<u>(1,261)</u>
Total comprehensive loss	<u>\$ (92,411)</u>	<u>\$ (113,138)</u>	<u>\$ (108,055)</u>

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Amount	Shares	Par Amount				
Balances at December 31, 2014	<u>26,307</u>	<u>\$ 26</u>	<u>43</u>	<u>\$ -</u>	<u>\$ 695,058</u>	<u>\$ (1,669)</u>	<u>\$ (592,933)</u>	<u>\$ 100,482</u>
Conversion of Preferred Stock	4,343	5	(43)	-	(3)	-	-	2
Issuance of common stock upon exercise of stock options and restricted stock awards	37	-	-	-	531	-	-	531
Issuance of common stock under Employee Stock Purchase Plan	23	-	-	-	291	-	-	291
Issuance of common stock, net of issuance costs	7,353	7	-	-	183,890	-	-	183,897
Warrants exercised	383	-	-	-	228	-	-	228
Stock compensation expense	-	-	-	-	9,703	-	-	9,703
Total other comprehensive loss	-	-	-	-	-	(1,261)	-	(1,261)
Net loss	-	-	-	-	-	-	(106,794)	(106,794)
Balances at December 31, 2015	<u>38,446</u>	<u>\$ 38</u>	<u>-</u>	<u>\$ -</u>	<u>\$ 889,698</u>	<u>\$ (2,930)</u>	<u>\$ (699,727)</u>	<u>\$ 187,079</u>
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	107	1	-	-	(84)	-	-	(83)
Issuance of common stock under Employee Stock Purchase Plan	46	-	-	-	615	-	-	615
Stock compensation expense	-	-	-	-	14,728	-	-	14,728
Total other comprehensive loss	-	-	-	-	-	(694)	-	(694)
Net loss	-	-	-	-	-	-	(112,444)	(112,444)
Balances at December 31, 2016	<u>38,599</u>	<u>\$ 39</u>	<u>-</u>	<u>\$ -</u>	<u>\$ 904,957</u>	<u>\$ (3,624)</u>	<u>\$ (812,171)</u>	<u>\$ 89,201</u>
Issuance of common stock upon exercise of stock options and restricted stock awards, net	262	-	-	-	1,613	-	-	1,613
Issuance of common stock under Employee Stock Purchase Plan	84	-	-	-	293	-	-	293
Issuance of common stock, net of issuance costs	22,588	23	-	-	185,913	-	-	185,936
Stock compensation expense	-	-	-	-	14,917	-	-	14,917
Total other comprehensive income	-	-	-	-	-	2,743	-	2,743
Net loss	-	-	-	-	-	-	(95,154)	(95,154)
Balances at December 31, 2017	<u>61,533</u>	<u>\$ 62</u>	<u>-</u>	<u>\$ -</u>	<u>\$ 1,107,693</u>	<u>\$ (881)</u>	<u>\$ (907,325)</u>	<u>\$ 199,549</u>

See accompanying notes.

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

	Year Ended December 31,		
	2017	2016	2015
Operating activities			
Net loss	\$ (95,154)	\$ (112,444)	\$ (106,794)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,244	2,257	1,365
Write-off of assets in progress	-	862	-
(Gain) loss on disposal of property and equipment	(10)	91	46
Accretion of discounts and amortization of premiums on marketable securities	(193)	178	660
Reversal of deferred rent upon lease amendment	(209)	-	-
Accretion of debt discount related to debt financing	-	-	(115)
Cash-settled portion of stock compensation expense	-	602	387
Stock compensation expense	14,917	14,126	9,316
Amortization of intangible assets	1,194	-	-
Loss on extinguishment of debt	-	-	1,671
Changes in operating assets and liabilities:			
Accounts and other receivables	488	52	(667)
Inventories	(312)	-	-
Prepaid expenses and other current assets	(1,830)	560	1,631
Restricted cash and other assets	(936)	(103)	(211)
Accounts payable	(1,915)	1,181	1,246
Accrued liabilities and other long term liabilities	3,198	(11,759)	9,017
Deferred revenues	-	(2,654)	(10,111)
Net cash used in operating activities	<u>(77,518)</u>	<u>(107,051)</u>	<u>(92,559)</u>
Investing activities			
Purchases of marketable securities	(227,672)	(126,754)	(208,936)
Proceeds from maturities of marketable securities	119,638	220,760	130,110
Purchases of property and equipment, net	(669)	(7,757)	(6,970)
Net cash (used in) provided by investing activities	<u>(108,703)</u>	<u>86,249</u>	<u>(85,796)</u>
Financing activities			
Proceeds from issuances of common stock, net	185,936	-	183,897
Payment of debt	-	-	(10,988)
Proceeds (withholding) from exercise of stock options and restricted stock awards, net	1,613	(84)	531
Proceeds from Employee Stock Purchase Plan	293	615	291
Proceeds from exercise of warrants	-	-	228
Net cash provided by financing activities	<u>187,842</u>	<u>531</u>	<u>173,959</u>
Effect of exchange rate changes on cash and cash equivalents	674	(252)	(303)
Net increase (decrease) in cash and cash equivalents	2,295	(20,523)	(4,699)
Cash and cash equivalents at beginning of year	24,289	44,812	49,511
Cash and cash equivalents at end of year	<u>\$ 26,584</u>	<u>\$ 24,289</u>	<u>\$ 44,812</u>
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	\$ -	\$ -	\$ 720
Accrual for litigation settlement and insurance recovery (Note 9)	\$ -	\$ 4,975	\$ -
Release of accrual for litigation settlement and insurance recovery (Note 9)	\$ 4,975	\$ -	\$ -
Return of unused development funding to AstraZeneca AB (Note 10)	\$ -	\$ 7,200	\$ -
Milestone payment from AstraZeneca AB (Note 10)	\$ -	\$ 7,200	\$ -
Non-cash investing and financing activities:			
Disposal of fully depreciated property and equipment	\$ 86	\$ 2,354	\$ 1,436
Net change in unrealized (loss) gain on marketable securities	<u>\$ (83)</u>	<u>\$ (8)</u>	<u>\$ 11</u>

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dynavax Technologies Corporation (“we,” “our,” “us,” “Dynavax” or the “Company”), is a fully-integrated biopharmaceutical company focused on leveraging the power of the body’s innate and adaptive immune responses through toll-like receptor (“TLR”) stimulation. Our first commercial product, HEPLISAV-B™ (Hepatitis B Vaccine (Recombinant), Adjuvanted), was approved by the United States Food and Drug Administration (“FDA”) in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology products are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1 safety study. 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) and include our accounts and those of our wholly-owned subsidiary, Dynavax GmbH located in Düsseldorf, Germany. All significant intercompany accounts and transactions among the entities have been eliminated from the consolidated financial statements. We operate in one business segment: the discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

As of December 31, 2017, we had cash, cash equivalents and marketable securities of \$191.9 million.

We have incurred significant operating losses and negative cash flows from our operations since our inception and we expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in (a) commercialization of HEPLISAV-B, (b) clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and (c) discovery research and development. Until we can generate a sufficient amount of revenue, if any, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Management’s estimates are based on historical information available as of the date of the consolidated financial statements and various other assumptions we believe are reasonable under the circumstances. Actual results could differ materially from these estimates.

Foreign Currency Translation

We consider the local currency to be the functional currency for our international subsidiary, Dynavax GmbH. Accordingly, assets and liabilities denominated in this foreign currency 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 during 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, 2017, 2016 and 2015, we reported an unrealized gain (loss) of \$2.8 million, \$(0.7) million and \$(1.3) million, respectively. Realized gains and losses resulting from currency transactions are included in other (expense) income in the consolidated statements of operations. For the years ended December 31, 2017, 2016 and 2015, we reported a (loss) gain of \$(0.6) million, \$0.2 million and \$0.1 million, respectively, resulting from currency transactions in our consolidated statements of operations.

Cash, Cash Equivalents and Marketable Securities

We consider all 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. In accordance with our investment policy, we invest in short-term money market funds, U.S. Treasuries, U.S. government agency securities and corporate debt securities. We believe these types of investments are subject to minimal credit and market risk.

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 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 investment 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 determine our segments based on the way we organize our business by making operating decisions and assessing performance. In fiscal years 2017, 2016 and 2015, 90%, 92% and 85% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Germany. As of December 31, 2017 and 2016, 15% and 17%, 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 the 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. Treasuries, U.S. government agency securities and corporate debt securities. We have not experienced any losses on our cash equivalents and marketable securities.

Our product candidates will require approval from the 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 may have a material adverse impact on our business and may impact our business in the future. In addition, after the approval of HEPLISAV-B by the FDA, there is still an ongoing risk of adverse events that did not appear during the drug approval process.

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

Inventories

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained.

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time we began to capitalize inventory costs associated with HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. At December 31, 2017, we had approximately 250,000 vials of pre-commercialization inventory of HEPLISAV-B which we expect to sell over at least the next nine months. We periodically analyze our inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements. Expired inventory will be disposed of and the related costs written off.

Intangible Assets

We record definite-lived intangible assets related to certain capitalized milestone payments. After determining that the pattern of future cash flows associated with intangible asset could not be reliably estimated with a high level of precision, we concluded that these assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of HEPLISAV-B's useful life is shorter than the remaining patent life, then the shorter period is used. We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. No impairment of intangible assets has been identified during 2017.

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. Additions, major renewals and improvements are capitalized and repair and maintenance costs are charged to expense as incurred. Leasehold improvements 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, 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, undiscounted future operating cash flows of long-lived assets are compared to their respective carrying value. If the carrying value is greater than the undiscounted future operating cash flows of long-lived assets, the long-lived assets are written down to their respective fair values and an impairment loss is recorded. Fair value is determined primarily using the discounted cash flows expected to be generated from the use of assets. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected cash flows. No impairments of tangible assets have been identified during the years presented.

Goodwill

Our goodwill balance relates to our April 2006 acquisition of Dynavax GmbH. Goodwill represents the excess purchase price over the fair value of tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized but is subject to an annual impairment test. In performing its goodwill impairment review, we assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount,

including goodwill. The qualitative factors include, but are not limited to macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If after assessing the totality of these qualitative factors, we determine that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, we will proceed to perform a test for goodwill impairment. The first step involves comparing the estimated 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. No impairments have been identified for the years presented.

Revenue Recognition

We recognize revenues from collaborations, grants and fees from services and licenses when 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. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit 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.

Non-refundable upfront fees received for license and collaborative agreements and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized on a ratable basis over our estimated performance period. Management makes its best estimate of the period over which we expect to fulfill our performance obligations. We recognize revenues for costs that are reimbursed under collaborative agreements as the related research and development costs are incurred.

Our license and collaboration agreements with our partners may provide for payments to be paid to us upon the achievement of milestones. Milestones are considered to be substantive if all of the following conditions are met: (i) 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. Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestones.

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. Royalty revenue is recognized when all revenue recognition criteria have been satisfied.

Revenue from government and private agency grants is recognized as the related research expenses are incurred and to the extent that funding is approved.

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 contracts with third parties 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, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is 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 estimates its research and development expenses and the related accrual 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, 2017.

Stock-Based Compensation

Stock-based compensation expense for restricted stock units and stock options is estimated at the grant date based on the award's estimated fair value and is recognized on a straight-line basis over the award's requisite service period, assuming estimated forfeiture rates. Fair value of restricted stock units is determined at the date of grant using the Company's closing stock price. Our determination of the fair value 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 subjective variables. 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 assumptions which determine the fair value-based measurement of stock options. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, 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 of stock options granted in the future. Changes in the fair value of stock awards could materially impact our operating results.

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 period of revision.

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. Tax law and rate changes are reflected in income in the period such changes are enacted. The Company includes interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

On December 22, 2017, President Trump signed U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which became effective January 1, 2018. The Tax Act significantly changes the fundamentals of U.S. corporate income taxation by, among many other things, reducing the U.S. federal corporate income tax rate to 21%, converting to a territorial tax system, and creating various income inclusion and expense limitation provisions. We have performed a review of the Tax Act, and based on information available at December 31, 2017, recorded certain provisional amounts related to the revaluation of our deferred taxes and the realization of certain tax credit carryforwards. Due to insufficient guidance on certain aspects of the Tax Act, such as officer's compensation, as well as uncertainty around the GAAP treatment associated with many other parts of the Tax Act, such as the implementation of certain international provisions, we cannot be certain that all deferred tax assets and liabilities have been established for the future effects of the legislation. Therefore, the final accounting for these provisions is subject to change as further information becomes available and further analysis is complete. Additionally, given the uncertainty and complexity of these new international tax regimes, we are continuing to evaluate how these provisions will be accounted for under U.S. generally accepted accounting principles; therefore, we have not yet adopted an accounting policy for treating the effects of these provisions as either a component of income tax expense in the period the tax arises, or through adjusting our deferred tax assets and liabilities to account for the estimated future impact of the special international tax regimes.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. We assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. We have provided a full valuation allowance on our deferred tax assets at December 31, 2017 and 2016 because we believe it is more likely than not that our deferred tax assets will not be realized as of December 31, 2017, and 2016.

The Company is required to file federal and state income tax returns in the United States and Germany. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect on such jurisdictions, which could impact the amount of tax paid by us. An amount is accrued for the estimate of additional tax liabilities, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. We update the accrual for uncertain tax positions as more definitive information becomes available.

Restructuring

Restructuring costs are comprised of severance costs related to workforce reductions. We recognize restructuring charges when the liability is incurred. Employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments.

Recent Accounting Pronouncements

Accounting Standards Update 2014-09

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which introduced Accounting Standards Codification ("ASC") 606, *Revenue Recognition, Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*, and provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods), with early application permitted. The FASB issued supplemental adoption guidance and clarification to ASU 2014-09 in March 2016, April 2016 and May 2016 within ASU 2016-08 "Revenue From Contracts With Customers: Principal vs. Agent Considerations," ASU 2016-10 "Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing," and ASU 2016-12 "Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients," respectively. We will adopt ASU 2014-09 on January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of that date. We have completed our analysis on the adoption of ASU 2014-09 of our revenues, identifying that there are no remaining performance obligations as of the adoption date. Based on this assessment, adopting this standard will not have a material impact on our consolidated financial statements and we do not expect to record any adjustment to accumulated deficit.

Accounting Standards Update 2016-02

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The ASU requires companies to recognize lease right-of-use assets and lease liabilities by lessees for all operating leases with lease terms greater than 12 months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The ASU is effective for annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis with early adoption permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements and believe the adoption will modify our analyses and disclosures of lease agreements considering operating leases are a significant portion of the Company's total lease commitments.

Accounting Standards Update 2016-18

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force). This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. The amendments in this update will be applied using a retrospective transition method to each period presented. The ASU is effective for annual periods beginning after December 15, 2018 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2017-04

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and other (Topic 350), which simplifies the test for goodwill impairment by eliminating a previous requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2017-09

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting. The ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The ASU is effective for annual periods beginning after December 15, 2017 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

3. Fair Value Measurements

The Company measures 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 valuation techniques and assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. There were no transfers between Level 1 and Level 2 during the twelve months ended December 31, 2017 and 2016.

The carrying amounts of cash equivalents, accounts and other receivables, accounts payable and accrued liabilities are considered reasonable estimates of their respective fair value because of their short-term nature.

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 (in thousands):

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
December 31, 2017				
Money market funds	\$ 22,543	\$ -	\$ -	\$ 22,543
U.S. Treasuries	-	45,534	-	45,534
U.S. government agency securities	-	86,820	-	86,820
Corporate debt securities	-	32,916	-	32,916
Total	<u>\$ 22,543</u>	<u>\$ 165,270</u>	<u>\$ -</u>	<u>\$ 187,813</u>
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
December 31, 2016				
Money market funds	\$ 18,981	\$ -	\$ -	\$ 18,981
U.S. Treasuries	-	3,499	-	3,499
U.S. government agency securities	-	30,437	-	30,437
Corporate debt securities	-	24,941	-	24,941
Total	<u>\$ 18,981</u>	<u>\$ 58,877</u>	<u>\$ -</u>	<u>\$ 77,858</u>

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is 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. Treasuries, U.S. Government agency securities and corporate debt 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

Cash, cash equivalents and marketable securities consist of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2017				
Cash and cash equivalents:				
Cash	\$ 4,041	\$ -	\$ -	\$ 4,041
Money market funds	22,543	-	-	22,543
Total cash and cash equivalents	26,584	-	-	26,584
Marketable securities available-for-sale:				
U.S. Treasuries	45,559	-	(25)	45,534
U.S. government agency securities	86,860	-	(40)	86,820
Corporate debt securities	32,931	-	(15)	32,916
Total marketable securities available-for-sale	165,350	-	(80)	165,270
Total cash, cash equivalents and marketable securities	\$ 191,934	\$ -	\$ (80)	\$ 191,854
December 31, 2016				
Cash and cash equivalents:				
Cash	\$ 3,557	\$ -	\$ -	\$ 3,557
Money market funds	18,981	-	-	18,981
U.S. government agency securities	1,751	-	-	1,751
Total cash and cash equivalents	24,289	-	-	24,289
Marketable securities available-for-sale:				
U.S. Treasuries	3,499	-	-	3,499
U.S. government agency securities	28,685	3	(2)	28,686
Corporate debt securities	24,938	5	(2)	24,941
Total marketable securities available-for-sale	57,122	8	(4)	57,126
Total cash, cash equivalents and marketable securities	\$ 81,411	\$ 8	\$ (4)	\$ 81,415

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

	December 31, 2017	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	\$ 165,350	\$ 165,270
Mature after one year through two years	-	-
	\$ 165,350	\$ 165,270

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2017, 2016 and 2015. All of our investments are classified as short-term and available-for-sale, as we consider them available to fund current operations and may not hold our investments until maturity.

5. Inventories

We began capitalizing inventory during the fourth quarter of 2017 in connection with the FDA's approval of HEPLISAV-B on November 9, 2017, as the related costs were expected to be recoverable through the commercialization of the product. Prior to the FDA's approval, costs to manufacture HEPLISAV-B were expensed as research and development expense as incurred, rather than capitalized as inventory as there was no alternative future use. At December 31, 2017, inventory consisted of work in progress of \$0.3 million. There was no write down related to excess or expiring inventory during 2017.

6. Intangible Assets

Intangible assets are related to certain capitalized milestone payments. The following table presents intangible assets (in thousands):

	December 31,	
	2017	2016
Intangible assets	\$ 2,500	\$ -
Less accumulated amortization	(1,194)	-
Total	\$ 1,306	\$ -

We recorded \$1.2 million in amortization expense related to intangible assets during the year ended December 31, 2017. See Note 10. At December 31, 2017, the intangible assets have an estimated remaining useful life of two months. The \$1.3 million balance will be fully amortized during the first quarter of 2018. No impairment of intangible assets has been identified during 2017.

7. Property and Equipment

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

	Estimated Useful Life (In years)	December 31,	
		2017	2016
Manufacturing equipment	5-14	\$ 12,104	\$ 10,086
Lab equipment	5-13	6,686	6,280
Computer equipment	3	4,760	4,010
Furniture and fixtures	3-13	1,629	1,566
Leasehold improvements	5-8(1)	10,873	8,942
Assets in progress		1,176	2,298
		37,228	33,182
Less accumulated depreciation and amortization		(20,609)	(16,008)
Total		\$ 16,619	\$ 17,174

(1) Leasehold improvements are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter.

Depreciation and amortization expense on property and equipment was \$3.2 million, \$2.3 million and \$1.4 million for the years ended December 31, 2017, 2016 and 2015, respectively.

8. Current Accrued Liabilities and Accrued Research and Development

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

	December 31,	
	2017	2016
Payroll and related expenses	\$ 6,180	\$ 3,753
Legal expenses	346	275
Litigation settlements accrual (Note 9)	-	4,975
Third party research expenses	3,567	2,784
Third party development expenses	522	2,002
Other accrued liabilities	3,439	2,451
Total	\$ 14,054	\$ 16,240

9. Commitments and Contingencies

We lease our facilities in Berkeley, California (“Berkeley Lease”) and Düsseldorf, Germany (“Düsseldorf Lease”) under operating leases that expire in December 2025 and March 2023, respectively. In May 2017, we amended the Berkeley Lease to extend the term of the lease to expire in December 2025 and to terminate the lease of an adjacent building. The early termination of the adjacent building’s lease did not result in a termination fee as the lease rate under the amended Berkeley Lease was determined to not be above market rates. In addition, as a result of the early termination, we reversed the deferred rent liability of \$0.2 million against rent expense in 2017. The amended Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the Berkeley Lease and Düsseldorf Lease is 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.

Total net rent expense related to our operating leases for the years ended December 31, 2017, 2016 and 2015, was \$2.4 million, \$2.2 million and \$2.0 million, respectively. Deferred rent was \$0.6 million and \$0.3 million as of December 31, 2017 and 2016, respectively. Accrued loss on lease was \$0.3 million as of December 31, 2016.

Future minimum payments under the non-cancelable portion of our operating leases and non-cancelable purchase commitments at December 31, 2017 are as follows (in thousands):

Year ending December 31,		
2018	\$	7,743
2019		2,559
2020		2,621
2021		2,549
2022		2,543
Thereafter		6,595
Total	\$	<u>24,610</u>

During 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, 2017, 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, 2017 and 2016. 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.

During 2004, we also established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of 0.2 million Euros. The letter of credit remained outstanding through December 31, 2017 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, 2017 and 2016.

We have entered into material long-term commitments with commercial manufacturers for the supply of HEPLISAV-B. To the extent these long-term commitments are non-cancelable, they are reflected in the above table.

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 also rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical material manufacturers. 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.

In conjunction with a financing arrangement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”) in November 2009, we agreed to make contingent cash payments to Holdings 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 cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. We have made no payments and have not recorded a liability as of December 31, 2017.

From time to time, we may be involved in claims, suits, and proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, commercial claims, and other matters. Such claims, suits, and proceedings are inherently uncertain and their results cannot be predicted with certainty. Regardless of the outcome, such legal proceedings can have an adverse impact on us because of legal costs, diversion of management resources, and other factors. In addition, it is possible that a resolution of one or more such proceedings could result in substantial damages, fines, penalties or orders requiring a change in our business practices, which could in the future materially and adversely affect our financial position, financial statements, results of operations, or cash flows in a particular period.

On September 7, 2016, we entered into a Stipulation of Settlement to settle the case entitled *In re Dynavax Technologies Securities Litigation* filed in 2013. The settlement, which was approved by the U.S. District Court for the Northern District of California on February 6, 2017, provided for a payment of \$4.1 million by us and results in a dismissal and release of all claims against all defendants, including us. The settlement was paid by our insurers in February 2017. The \$4.1 million accrued liability and corresponding \$4.1 million prepaid expenses and other current assets reflected in our consolidated balance sheet as of December 31, 2016 were released during the first quarter of 2017.

On October 24, 2017, we entered into a Stipulation of Settlement to settle the derivative case filed in 2013. The settlement provided for a payment of \$0.9 million by us and results in a dismissal and release of all claims against all defendants, including us. The settlement was paid by our insurers in November 2017. The \$0.9 million accrued liabilities and corresponding \$0.9 million prepaid expenses and other current assets reflected in our consolidated balance sheets as of December 31, 2016 were released during the fourth quarter of 2017.

Amounts recorded for contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. For information about the risks associated with estimates and assumptions, see Use of Estimates in Note 2.

10. Collaborative Research, Development and License Agreements

AstraZeneca

Pursuant to a research collaboration and license agreement with AstraZeneca AB (AstraZeneca”), as amended, we discovered and performed initial clinical development of AZD1419, a TLR9 agonist product candidate for the treatment of asthma. In June 2016, all of our remaining performance obligations under our agreement with AstraZeneca were completed.

In November 2016, AstraZeneca initiated the Phase 2a trial of AZD1419 in asthma patients. Upon AstraZeneca’s initiation of the Phase 2a trial, we earned a milestone payment of \$7.2 million, which was offset against \$7.4 million in unused development funding previously advanced by AstraZeneca. We recognized the \$7.2 million milestone as revenue during the fourth quarter of 2016. The remaining balance of unused development funding, net of the \$7.2 million milestone payment, was \$0.2 million which was paid during the first quarter of 2017. No liability related to unused development funding remains on the accompanying consolidated balance sheet as of December 31, 2017.

Under the terms of the agreement, as amended, we are eligible to receive up to approximately \$100 million in additional milestone payments, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization of AZD1419, 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.

The following table summarizes the revenues earned under our agreement with AstraZeneca, included as collaboration revenue in our consolidated statements of operations (in thousands):

	Year ended December 31,		
	2017	2016	2015
Initial and milestone payment	\$ -	\$ 7,722	\$ 238
Subsequent payment	-	1,953	892
Performance of research activities	-	103	1,635
Total	<u>\$ -</u>	<u>\$ 9,778</u>	<u>\$ 2,765</u>

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.

Coley Pharmaceutical Group, Inc.

In June 2007, we entered into a license agreement with Coley Pharmaceutical Group, Inc. ("Coley"), under which Coley granted us a non-exclusive, royalty bearing license to patents, with the right to grant sublicenses for HEPLISAV-B. Under the terms of this agreement, we are responsible for royalties in the low single-digit based on product sales arising from the license. We met one of the regulatory milestones upon FDA approval of HEPLISAV-B in November 2017 and recorded \$2.5 million as an intangible asset on the consolidated balance sheets. See Note 6. At December 31, 2017, the \$2.5 million payment due to Coley was included in accounts payable on the consolidated balance sheet. The agreement continues in effect through February 2018, at which time the license becomes a perpetual, irrevocable, fully paid-up and royalty free license. No further milestone payments are expected prior to termination.

11. Long-Term Debt

Note Purchase Agreement

In October 2016, we entered into a Note Purchase Agreement pursuant to which the Company would borrow \$100.0 million upon approval of HEPLISAV-B. The Company paid the prospective lender \$1.0 million upon entering into the Note Purchase Agreement and incurred additional expenses of \$1.6 million in securing the Note Purchase Agreement. No notes were ultimately sold by the Company under the Note Purchase Agreement.

In December 2016, the Company terminated the Note Purchase Agreement and paid a termination fee of \$1.5 million. The \$1.0 million paid upon entering in the note purchase agreement and \$1.5 million termination fee are included in other expense in the consolidated statements of operations. The additional expenses of \$1.6 million related to securing the Note Purchase Agreement are included in loss from operations in the consolidated statement of operations.

Hercules Loan and Security Agreement

In December 2014, we entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules") under which we could borrow up to \$40.0 million in two tranches. We drew down the first tranche of \$10.0 million upon closing of the transaction on December 23, 2014. The second tranche, of \$30.0 million, was available to be drawn at our option any time prior to September 30, 2015. No additional amounts were drawn down under the terms of the Loan Agreement.

In September 2015, we repaid all outstanding amounts under the Loan Agreement, at which time our obligations under the Loan Agreement terminated and Hercules released its security interests in all collateral under the Loan Agreement. We paid to Hercules \$11.0 million, which consisted of \$10.0 million outstanding principal, accrued but unpaid interest of \$38 thousand, end of term fee of \$0.8 million and prepayment charges of \$0.2 million. We recognized the repayment to be a substantial modification to the debt instrument and applied debt extinguishment accounting to record a one-time loss on extinguishment of debt in the amount of \$1.7 million.

12. Net Loss Per Share

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

	December 31,		
	2017	2016	2015
Basic and diluted net loss per share (in thousands, except per share amounts):			
Numerator:			
Net loss	\$ (95,154)	\$ (112,444)	\$ (106,794)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	52,613	38,506	32,881
Basic and diluted net loss per share	\$ (1.81)	\$ (2.92)	\$ (3.25)

Outstanding stock options and 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,		
	2017	2016	2015
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Stock options and stock awards	5,981	4,673	3,086
Total	5,981	4,673	3,086

13. Common Stock

Common Stock Outstanding

As of December 31, 2017, there were 61,532,812 shares of our common stock outstanding.

On November 3, 2017, we entered into an At Market Sales Agreement (“2017 ATM Agreement”) with Cowen and Company, LLC (“Cowen”) under which we may offer and sell from time to time at our sole discretion, shares of our common stock having an aggregate offering price up to \$150 million through Cowen as our sales agent. We pay Cowen a commission of up to 3% of the gross sales proceeds of any common stock sold through Cowen under the 2017 ATM Agreement. As of December 31, 2017, we received net cash proceeds of \$16.9 million resulting from sales of 840,774 shares of our common stock.

In August 2017, we completed an underwritten public offering of 5,750,000 shares of our common stock, including 750,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters. All of the shares were offered at a price to the public of \$15.00 per share. The net proceeds to us from this offering were approximately \$80.8 million, after deducting the underwriting discount and other estimated offering expenses payable by us.

As of December 31, 2017, we received net cash proceeds of \$88.2 million from sales of 15,997,202 shares of our common stock under a now terminated At Market Sales Agreement (“2015 ATM Agreement”).

14. Equity Plans and Stock-Based Compensation

Stock Plans

Under the 2004 Stock Incentive Plan (“2004 Plan”) options to purchase 77,774 shares of common stock remained outstanding as of December 31, 2017.

Under the 2010 Employment Inducement Award Plan (“2010 Inducement Plan”) options to purchase 11,450 shares of common stock remained outstanding as of December 31, 2017.

The 2011 Equity Incentive Plan (“2011 Plan”) was approved by the Company’s stockholders and adopted in January 2011. On June 2, 2017, the stockholders of the Company approved an amendment and restatement of the 2011 Plan to increase the number of shares of common stock authorized for issuance under the plan by 1,600,000. The 2011 Plan, as amended, provides for the issuance of up to 10,343,442 shares of our common stock to employees and non-employees of the Company. 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 7 or 10 years unless earlier terminated by the Board of Directors. As of December 31, 2017, options to purchase 3,373,555 shares of common stock remained outstanding under the 2011 Plan. As of December 31, 2017, there were 2,100,333 shares of common stock reserved for issuance under the 2011 Plan.

On November 28, 2017, the Company adopted the Dynavax Technologies Corporation Inducement Award Plan (the “2017 Inducement Plan”), pursuant to which the Company reserved 1,200,000 shares of its common stock for issuance under the 2017 Inducement Plan to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual’s entry into employment with the Company within the meaning of Nasdaq Listing Rule 5635(c)(4). As of December 31, 2017, there were 1,125,200 shares of common stock reserved for issuance under the 2017 Inducement Plan.

Activity under our stock plans is set forth below:

	Shares		Weighted-Average		Aggregate
	Underlying Outstanding	Weighted-Average Exercise	Remaining	Contractual Term	Intrinsic Value
	Options (in thousands)	Price Per Share	Contractual Term	(years)	(in thousands)
Balance at December 31, 2016	3,975	\$ 21.38			
Options granted	535	12.23			
Options exercised	(144)	14.28			
Options cancelled:					
Options forfeited (unvested)	(400)	18.30			
Options cancelled (vested)	(411)	30.78			
Balance at December 31, 2017	<u>3,555</u>	<u>\$ 19.56</u>	<u>6.04</u>		<u>\$ 7,477</u>
Vested and expected to vest at December 31, 2017	<u>3,533</u>	<u>\$ 19.56</u>	<u>6.04</u>		<u>\$ 7,468</u>
Exercisable at December 31, 2017	<u>2,294</u>	<u>\$ 21.35</u>	<u>5.77</u>		<u>\$ 2,702</u>

The total intrinsic value of stock options exercised during the years ended December 31, 2017, 2016 and 2015 was \$0.9 million, \$0.2 million and \$0.4 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, 2017, 2016 and 2015 was \$13.0 million, \$12.1 million and \$6.9 million, respectively.

Our non-vested stock awards are comprised of restricted stock units granted with performance and time-based vesting criteria. A summary of the status of non-vested restricted stock units as of December 31, 2017, and activities during 2017 are summarized as follows:

	Number of Shares (In thousands)	Weighted-Average Grant- Date Fair Value
Non-vested as of December 31, 2016	699	\$ 12.12
Granted	2,217	5.34
Vested	(188)	18.24
Forfeited	(285)	7.74
Non-vested as of December 31, 2017	2,443	\$ 6.01

Stock-based compensation expense related to restricted stock units was approximately \$5.5 million for the year ended December 31, 2017. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2017, based on our stock price on that date, was \$45.7 million.

The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2017, 2016 and 2015 was, \$5.34, \$12.42 and \$20.05, respectively. The total fair value of restricted stock units vested during the years ended December 31, 2017, 2016 and 2015 was \$1.2 million, \$1.0 million and \$0.1 million, respectively.

Stock-Based Compensation

Under our stock-based compensation plans, option awards generally vest over a four-year or three-year period contingent upon continuous service and unless exercised, expire seven or 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 2017 Inducement and 2011 Plans. As of December 31, 2017, approximately 60,000 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			Employee Stock Purchase Plan		
	Year Ended December 31,			Year Ended December 31,		
	2017	2016	2015	2017	2016	2015
Weighted-average fair value	\$ 8.27	\$ 9.54	\$ 13.37	\$ 3.05	\$ 7.86	\$ 9.18
Risk-free interest rate	1.9%	1.4%	1.7%	1.0%	0.6%	0.4%
Expected life (in years)	4.5	4.9	5.9	1.2	1.2	1.2
Expected Volatility	0.9	0.7	0.7	1.0	0.6	0.6

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. 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. Forfeiture estimates are based on historical employee turnover. 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,		
	2017	2016	2015
Employees and directors stock-based compensation expense	\$ 14,917	\$ 14,126	\$ 9,316

	Year Ended December 31,		
	2017	2016	2015
Research and development	\$ 7,827	\$ 6,742	\$ 4,123
Selling, general and administrative	7,090	7,384	5,193
Total	\$ 14,917	\$ 14,126	\$ 9,316

In addition, the cash-settled portion of stock compensation expense was \$0.6 million and \$0.4 million for the years ended December 31, 2016 and 2015, respectively. No cash-settled portion of stock compensation expense was incurred during 2017.

As of December 31, 2017, the total unrecognized compensation cost related to non-vested stock options and awards deemed probable of vesting, including all stock options with time-based vesting, net of estimated forfeitures, amounted to \$21.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years. Additionally, as of December 31, 2017, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to \$0.3 million.

Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan, as amended, (the "Purchase Plan") provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. 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 sixteenth 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 fifteenth day in February or August). For the year ended December 31, 2017, employees have acquired 84,247 shares of our common stock under the Purchase Plan and 98,227 shares of our common stock remained available for future purchases under the Purchase Plan.

As of December 31, 2017, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan amounted to \$0.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.2 years.

15. 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. The Company's contribution to the 401(k) Plan was approximately \$0.2 million for the years ended December 31, 2017, 2016 and 2015.

16. Restructuring

In January 2017, we implemented organizational restructuring and cost reduction plans to align around our immuno-oncology business while allowing us to advance HEPLISAV-B through the FDA review and approval process. To achieve these cost reductions, we suspended manufacturing activities, commercial preparations and other long term investment related to HEPLISAV-B and reduced our global workforce by approximately 40 percent. In the first quarter of 2017 we recorded charges of \$2.8 million related to severance, other termination benefits and outplacement services. As of December 31, 2017, all of the \$2.8 million was paid.

17. Income Taxes

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

	Year Ended December 31,		
	2017	2016	2015
U.S.	\$ (95,898)	\$ (114,484)	\$ (107,450)
Non U.S.	744	2,040	656
Total	\$ (95,154)	\$ (112,444)	\$ (106,794)

No income tax expense was recorded for the years ended December 31, 2017, 2016 and 2015 due to net operating loss carryforwards to offset the net income at Dynavax GmbH 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,		
	2017	2016	2015
Income tax benefit at federal statutory rate	\$ (32,352)	\$ (38,183)	\$ (36,301)
State tax	(4,482)	(334)	(394)
Business credits	(1,960)	(1,950)	(2,622)
Deferred compensation charges	3,823	3,016	1,481
Change in valuation allowance	(109,165)	36,751	36,766
Rate change	86,943	-	-
Net operating loss and tax credit limitation	56,962	-	-
Other	231	700	1,070
Total income tax expense	\$ -	\$ -	\$ -

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

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carry forwards	\$ 146,300	\$ 249,510
Research tax credit carry forwards	29,658	29,463
Accruals and reserves	6,551	8,684
Capitalized research costs	1,422	4,457
Other	731	1,303
Total deferred tax assets	184,662	293,417
Less valuation allowance	(184,388)	(293,145)
Net deferred tax assets	274	272
Deferred tax liabilities:		
Fixed assets	(274)	(272)
Total deferred tax liabilities	(274)	(272)
Net deferred tax assets	\$ -	\$ -

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 decreased by \$108.8 million during the year ended December 31 2017 and increased by \$36.4 million and \$36.2 million during the years ended December 31, 2016 and 2015, respectively.

On December 22, 2017, the Tax Act was signed into law. Among other changes is a permanent reduction in the federal corporate income tax rate from 35% to 21% effective January 1, 2018. As a result of the reduction in the corporate income tax rate, the Company has revalued its net deferred tax assets at December 31, 2017. We estimate that this will result in a reduction in the value of our net deferred tax assets of approximately \$87 million, which will be offset by the change in valuation allowance of \$87 million.

The Tax Act also adopts elements of a territorial tax system while assessing a repatriation tax or “toll-charge” on undistributed earnings and profits of U.S.-owned foreign corporations. At this time, management has estimated the repatriation of undistributed earnings and profits of U.S. owned foreign corporations will result in a provisional income inclusion of \$0.7 million, which will be fully offset by a current year loss. Other than the U.S. taxation of these amounts, we intend to continue to invest these earnings indefinitely outside of the U.S. and do not expect to incur any additional taxes related to such amounts.

As of December 31, 2017, we had federal net operating loss carryforwards of approximately \$629.1 million, which will expire in the years 2018 through 2037 and federal research and development tax credits of approximately \$16.9 million, which expire in the years 2018 through 2037.

As of December 31, 2017, we had net operating loss carryforwards for California and other states for income tax purposes of approximately \$168.4 million, which expire in the years 2026 through 2037, and California state research and development tax credits of approximately \$17.4 million, which do not expire.

As of December 31, 2017, we had net operating loss carryforwards for foreign income tax purposes of approximately \$15.5 million, which do not expire.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits was \$1.2 million and \$2.4 million as of December 31, 2017 and 2016, respectively. If recognized, none of the unrecognized tax benefits would affect the effective tax rate.

The following table summarizes the activity related to the Company’s unrecognized tax benefits:

Balance at December 31, 2016	\$	(2,426)
Tax positions related to the current year		
Additions		-
Reductions		-
Tax positions related to the prior year		
Additions		-
Reductions		1,197
Balance at December 31, 2017	\$	(1,229)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2017, the Company had no interest related to unrecognized tax benefits. No amounts of penalties related to unrecognized tax benefits were recognized in the provision for income taxes. We do not anticipate any significant change within 12 months of this reporting date of its uncertain tax positions.

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. Based on an analysis under Section 382 of the Internal Revenue Code, the Company experienced ownership changes in 2008, 2009 and 2012 which limit the future use of its pre-change federal net operating loss carryforwards and federal research and development tax credits. The Company has excluded these federal net operating loss carryforwards and federal research and development tax credits that will expire as a result of the annual limitations in the deferred tax assets as of December 31, 2017. A limitation calculation has not been performed with respect to the California net operating loss carryforwards and research and development tax credits and we believe that our ability to use these California net operating loss carryforwards and research and development tax credits in the future may be limited.

We are subject to income tax examinations for U.S. federal and state income taxes from 1998 forward. We are subject to tax examination in Germany from 2014 forward.

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

	Year Ended December 31, 2017			
	Q1	Q2	Q3	Q4
Revenues	\$ 148	\$ 105	\$ 53	\$ 21
Net loss	\$ (25,287)	\$ (20,318)	\$ (22,128)	\$ (27,421)
Basic and diluted net loss per share	\$ (0.60)	\$ (0.41)	\$ (0.38)	\$ (0.45)
Shares used to compute basic and diluted net loss per share	41,830	49,700	57,650	61,007

	Year Ended December 31, 2016			
	Q1	Q2	Q3	Q4
Revenues	\$ 942	\$ 2,647	\$ 162	\$ 7,292
Net loss	\$ (27,023)	\$ (28,986)	\$ (34,694)	\$ (21,741)
Basic and diluted net loss per share	\$ (0.70)	\$ (0.75)	\$ (0.90)	\$ (0.56)
Shares used to compute basic and diluted net loss per share	38,472	38,496	38,512	38,544

19. Subsequent Events

HEPLISAV-B

We commenced commercial shipments of HEPLISAV-B in the first quarter of 2018. On February 21, 2018, the Centers for Disease Control and Prevention's ("CDC") Advisory Committee on Immunization Practices ("ACIP") voted unanimously in favor of including HEPLISAV-B on its list of ACIP recommended products for use to vaccinate adults against hepatitis B.

Term Loan Agreement

On February 20, 2018, we entered into a \$175.0 million term loan agreement ("Loan Agreement") with CRG Servicing LLC. The Loan Agreement provides for a \$175.0 million term loan facility, \$100.0 million of which was borrowed at closing and, subject to the satisfaction of certain market capitalization and other borrowing conditions, up to an additional \$75.0 million at our option on or before July 17, 2019.

The loans have a maturity date of December 31, 2023, unless earlier prepaid. The loans bear interest at a rate equal to 9.50% per annum.

Sublicense Agreement

On February 16, 2018, we entered into a Sublicense Agreement (the "Sublicense Agreement") with Merck Sharpe & Dohme Corp. (the "Sublicensor"). The Sublicense Agreement grants us, under certain non-exclusive U.S. patent rights controlled by the Sublicensor which relate to recombinant production of Hepatitis B surface antigen, the right to manufacture, use, offer for sale, sell and import HEPLISAV-B, adult Hepatitis B Vaccine, to prevent hepatitis B and diseases caused by hepatitis B in the United States and includes the right to grant further sublicenses. In consideration, we made a \$7.0 million payment to the Sublicensor in February 2018. The remaining two payments of \$7.0 million each are due in the first quarter of each of 2019 and 2020.

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 of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, concluded that our disclosure controls and procedures are effective and were operating 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 Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2017. 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 a report on the Company’s internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

To the Stockholders and the Board of Directors of Dynavax Technologies Corporation

Opinion on Internal Control over Financial Reporting

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control— Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Dynavax Technologies Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, 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, 2017 and the related notes of the Company and our report dated March 8, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company'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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control Over Financial Reporting

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.

/s/ Ernst & Young LLP

San Francisco, California
March 8, 2018

(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.

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 2018 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, 2017.

We have adopted the Dynavax Code of Business Conduct and Ethics (“Code of Conduct”), a code of ethics that applies to our employees, including our Chief Executive Officer, Chief Financial Officer and to our non-employee directors. The Code of Conduct is publicly available on our website under the Investors and Media 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 Chief 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 Program,” “Director Compensation,” “Compensation Discussion and Analysis,” “Report of the Compensation Committee of the Board of Directors on Executive Compensation,” “Outstanding Equity Awards at Fiscal Year End” 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 “Certain Transactions With or Involving 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.

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

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

(b) Exhibits

Incorporated by Reference

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Amended and Restated Bylaws	3.2	S-1/A	February 5, 2004	333-109965	
3.3	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	3.3	8-K	November 6, 2008	000-50577	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	

Incorporated by Reference

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
3.9	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	
4.1	Reference is made to Exhibits 3.1 , 3.2 , 3.3 , 3.4 , 3.5 , 3.6 , 3.7 , 3.8 and 3.9 above					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.3	Rights Agreement, dated as of November 5, 2008, by and between the Company and Mellon Investor Services LLC	4.4	8-K	November 6, 2008	000-50577	
4.4	Form of Right Certificate	4.5	8-K	November 6, 2008	000-50577	
4.5	Form of Restricted Stock Unit Award Agreement under the 2004 Stock Incentive Plan	4.6	10-K	March 6, 2009	001-34207	
10.01†	Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB	10.30	10-Q	November 3, 2006	000-50577	
10.02	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company	10.2	10-Q	November 3, 2017	001-34207	
10.03†	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	10.40	10-Q	April 30, 2009	001-34207	
10.04	Amended and Restated Purchase Option Agreement, dated November 9, 2009, between the Company and Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.	10.47	10-K	March 16, 2010	001-34207	
10.05	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	10.54	8-K	October 4, 2010	001-34207	

Incorporated by Reference

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.6	Lease, dated January 7, 2004, between the Company and 2929 Seventh Street, LLC	10.17	S-1/A	January 16, 2004	333-109965	
10.7	First Amendment to Lease, dated as of May 21, 2004, between the Company and 2929 Seventh Street, LLC	10.55	8-K	October 13, 2010	001-34207	
10.8	Second Amendment to Lease, dated as of October 12, 2010, between the Company and 2929 Seventh Street, LLC	10.56	8-K	October 13, 2010	001-34207	
10.9+	Amended and Restated 2011 Equity Incentive Plan	99.1	S-8	June 1, 2016	333-211747	
10.10+	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan	99.2	S-8	January 6, 2011	333-171552	
10.11+	Form of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan	99.3	S-8	January 6, 2011	333-171552	
10.12	Third Amendment to Lease, dated as of April 1, 2011, between the Company and 2929 Seventh Street, LLC	10.65	10-Q	August 3, 2011	001-34207	
10.13†	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	10.67	10-K	March 12, 2012	001-34207	
10.14	Fourth Amendment to Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC	10.72	10-K	March 8, 2013	001-34207	
10.15	Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC	10.73	10-K	March 8, 2013	001-34207	
10.16+	Employment Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company	10.78	8-K	May 3, 2013	001-34207	

Incorporated by Reference

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.17+	Management Continuity and Severance Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company.	10.79	8-K	May 3, 2013	001-34207	
10.18†	Amendment No. 5 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated January 7, 2014	10.88	10-K	March 10, 2014	001-34207	
10.19+	Employment Agreement, dated March 6, 2013, by and between David Novack and the Company.	10.84	10-K	March 10, 2014	001-34207	
10.20+	Employment Agreement, dated July 12, 2013, by and between Robert Janssen, M.D. and the Company.	10.85	10-K	March 10, 2014	001-34207	
10.21+	Employment Agreement, dated February 4, 2014, by and between David L. Johnson and the Company.	10.86	10-K	March 10, 2014	001-34207	
10.22+	Amended and Restated 2014 Employee Stock Purchase Plan	99.4	S-8	June 1, 2016	333-211747	
10.23+	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, Amended February 5, 2015	10.35	10-K	March 5, 2015	001-34207	
10.24†	Amendment No. 6 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, effective as of December 8, 2014	10.36	10-K	March 5, 2015	001-34207	
10.25	Amendment No. 7 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, effective as of January 13, 2016	10.29	10-K	March 8, 2016	001-34207	

Incorporated by Reference

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.26+	Form of Amended and Restated Management Continuity and Severance Agreement between the Company and certain of its executive officers	10.1	8-K	April 19, 2016	001-34207	
10.27	Fifth Amendment to Lease, dated as of May 15, 2017, between the Company and 2929 Seventh Street, LLC	10.2	10-Q	August 7, 2017	001-34207	
10.28	Sales Agreement, dated November 3, 2017, between the Company and Cowen and Company, LLC	10.1	10-Q	November 3, 2017	001-34207	
10.29	2017 Inducement Award Plan	10.1	8-K	November 30, 2017	001-34207	
10.30^	Master Services Agreement, dated January 11, 2016, between the Company and inVentiv Commercial Services, LLC					X
10.31^	Project Agreement, dated October 31, 2017 between the Company and inVentiv Commercial Services, LLC					X
10.32^	First Amendment to Project Agreement, dated October 31, 2017 between Company and inVentiv Commercial Services, LLC					X
10.33^	Commercial Manufacturing and Supply Agreement, dated November 22, 2013, between Company and Baxter Pharmaceutical Solutions LLC					X
10.34^	Supply Agreement, dated November 2, 2016, between Company and Becton, Dickinson and Company.					X
10.35^	Supply Agreement, dated October 1, 2012, between Company and Nitto Denko AVECIA, Inc.					X
10.36^	Supply Agreement, dated July 27, 2016, between Company and West Pharmaceutical Services, Inc.					X

Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges					X
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Chief Executive Officer to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

EX—101.INS XBRL Instance Document
 EX—101.SCH XBRL Taxonomy Extension Schema Document
 EX—101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
 EX—101.DEF XBRL Taxonomy Extension Definition Linkbase
 EX—101.LAB XBRL Taxonomy Extension Labels Linkbase Document
 EX—101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

† 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, compensatory plan or arrangement.

* 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.

^ We have requested confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY

None.

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

By: _____ /s/ EDDIE GRAY

Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2018

By: _____ /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: March 8, 2018

By: _____ /s/ DAVID JOHNSON

David Johnson
Vice President, Chief Accounting Officer
(Principal Accounting Officer)

Date: March 8, 2018

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ EDDIE GRAY _____ Eddie Gray	Chief Executive Officer <i>(Principal Executive Officer)</i>	March 8, 2018
/s/ MICHAEL OSTRACH _____ Michael Ostrach	Chief Financial Officer <i>(Principal Financial Officer)</i>	March 8, 2018
/s/ DAVID JOHNSON _____ David Johnson	Vice President, Chief Accounting Officer <i>(Principal Accounting Officer)</i>	March 8, 2018
/s/ ARNOLD L. ORONSKY, PH.D. _____ Arnold L. Oronsky, Ph.D.	Chairman of the Board	March 8, 2018
/s/ LAURA BREGE _____ Laura Brege	Director	March 8, 2018
/s/ FRANCIS R. CANO, PH.D. _____ Francis R. Cano, Ph.D.	Director	March 8, 2018
/s/ DENNIS A. CARSON, M.D. _____ Dennis A. Carson, M.D.	Director	March 8, 2018
/s/ DANIEL L. KISNER, M.D. _____ Daniel L. Kisner, M.D.	Director	March 8, 2018
/s/ PEGGY V. PHILLIPS _____ Peggy V. Phillips	Director	March 8, 2018
/s/ STANLEY A. PLOTKIN, M.D. _____ Stanley A. Plotkin, M.D.	Director	March 8, 2018
/s/ NATALE S. RICCIARDI _____ Natale S. Ricciardi	Director	March 8, 2018

MASTER SERVICE AGREEMENT

This Master Service Agreement (this “Agreement”) is made as of January 11, 2016 (the “Effective Date”) by and between inVentiv Commercial Services, LLC, a New Jersey limited liability company with an office located at 500 Atrium Drive, Somerset, NJ 08873 (“inVentiv”) and Dynavax Technologies Corporation, a Delaware Corporation with an office located at 2929 Seventh Street, Suite 100, Berkeley, CA 94710 (“Client”). Client and inVentiv may each be referred to herein as a “Party” and collectively, the “Parties”.

RECITALS

A. inVentiv and its Affiliates (as defined herein) offer a wide range of services and offerings to clients in the pharmaceutical and biotechnology arena.

B. Client hereby engages inVentiv, and inVentiv hereby accepts such engagement, to provide various types of services pursuant to the terms hereof and each separate project agreement in the form attached hereto as Exhibit A (each a “Project Agreement”) to be executed by the Parties. Client and inVentiv shall enter into a Project Agreement for each program they wish to be governed by the terms and conditions of this Agreement.

1. Interpretation and Construction

(a) The Parties desire for the terms and conditions set forth in this Agreement to govern the relationship between the Parties. Unless otherwise specifically set forth in a Project Agreement, in the event of a conflict or inconsistency between the terms and conditions set forth in this Agreement and the terms and conditions set forth in a Project Agreement, the terms and conditions set forth in this Agreement shall take precedence, govern and control.

(b) The Parties hereby acknowledge that the terms set forth in this Agreement shall be incorporated by reference into each Project Agreement, as if fully set forth at length therein.

(c) The Parties acknowledge that in addition to inVentiv, certain or inVentiv’s Affiliates may provide certain services to Client and may directly enter into a Project Agreement with Client, subject to Client’s prior written consent, pursuant to which such inVentiv Affiliate shall provide certain services to Client, as set forth in detail in said executed Project Agreement. In such event, the Project Agreement shall confirm that this Agreement shall govern the relationship between Client and the particular inVentiv Affiliate, and such parties agree to be bound by the terms set forth herein. Client agrees that inVentiv acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of any inVentiv Affiliate under any circumstances in connection with any Project Agreement that is not signed by inVentiv. Further, each inVentiv Affiliate acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of inVentiv or any other inVentiv Affiliate under any circumstances in connection with this Agreement or any Project Agreement that is not signed by that inVentiv Affiliate. As used in this Agreement, the term Affiliate means, with respect to any entity, any other entity directly or indirectly, through one or more intermediaries,

controlling, controlled by or under common control with such entity. As used in this definition, the term “control” (including “controlled by” or “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, as trustee, by contract or otherwise.

2. The Services

(a) Client shall retain inVentiv to provide services as set forth in one or more Project Agreements (hereinafter the “Services”).

(b) Client has no obligation to inVentiv for Services under this Agreement in the absence of an executed Project Agreement covering such Services.

(c) Each Project Agreement shall allocate responsibility for project management and quality assurance activities necessary to perform the Services. inVentiv will provide regular updates as to the progress of the Services at a frequency and in a manner designated by the Parties in the Project Agreement.

3. Representations and Warranties of the Parties

(a) inVentiv represents, warrants and covenants that:

(i) it shall perform the Services in a professional, workmanlike manner and in accordance with those specifications which inVentiv and Client agree to (in writing), any timelines agreed upon (in writing);

(ii) it shall maintain in full force and effect all necessary licenses, permits, approvals (or waivers) and authorizations required by law to carry out its obligations under this Agreement and any Project Agreement;

(iii) the execution, delivery and performance of this Agreement by inVentiv and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; that the Agreement constitutes the legal, valid, and binding obligation of inVentiv, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors’ rights generally and by general principles of equity); and that this Agreement and performance hereunder does not violate or constitute a breach under any organizational document of inVentiv or any contract, other form of agreement, or judgment or order to which inVentiv is a party or by which it is bound;

(iv) the personnel assigned to perform Services rendered under this Agreement and any Project Agreement shall be capable professionally and duly qualified to perform the Services hereunder and in each Project Agreement;

(v) it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and that during the term of this Agreement, it will not enter

2.

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

into any agreement to provide services which would in any way prevent it from performing the Services under this Agreement; and

(vi) the Services shall be provided in compliance with all statutes, federal and state applicable laws, ordinances, rules or regulations of any governmental or regulatory authority including (but not limited to) the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code on interactions with Healthcare Professionals, the Accreditation Council for Continuing Medical Education requirements for continuing medical education, the American Medical Association Ethical Guidelines on Gifts to Physicians from Industry, the Federal Food, Drug and Cosmetic Act (“FDCA”), the Medicare/Medicaid anti-kickback statute, the Prescription Drug Marketing Act (“PDMA,”), the Health Insurance Portability and Accountability Act, and similar state laws, rules and regulations (collectively, “Applicable Law”).

(b) Client represents, warrants and covenants that:

(i) the execution, delivery and performance of this Agreement by Client and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; that the Agreement constitutes the legal, valid, and binding obligation of Client, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors’ rights generally and by general principles of equity); and that this Agreement and, performance hereunder does not violate or constitute a breach under any organizational document of Client or any contract, other fonts of agreement, or judgment or order to which. Client is a party or by which it is bound;

(ii) Client shall apply the degree of skill, care necessary to provide inVentiv with the information and materials necessary for inVentiv to provide the Services and deliverables that will be of high quality, proper and sufficient for the purpose contemplated, and in accordance with the standards of care and diligence regularly practiced by pharmaceutical companies contracting to receive the same or similar services.

(iii) Client will act in good faith to provide inVentiv with the necessary materials, information, product training, and assistance required to enable inVentiv to perform the Services in compliance with all Applicable Law. Certain Client obligations and responsibilities unique to a specific Project Agreement shall be specified within that Project Agreement;

(iv) Client shall ensure all content (product or otherwise), materials, documentation and information provided by it to inVentiv are in compliance with Applicable Law;

(v) Client shall provide any and all necessary training regarding the Client product(s) and shall be responsible for all costs and expenses of such training, including inVentiv personnel travel, lodging, meals, and miscellaneous;

(vi) Client’s products shall be promoted under trademarks owned by or licensed to Client and are products which are either owned by Client and/or as to which Client

3.

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

has all lawful authority necessary to market and sell the products. Client represents and warrants that its trademarks, trade names and trade dress do not infringe on any intellectual property or product marketing rights of any other person or entity. Client further represents and warrants that the promotion of any Client product by inVentiv does not infringe on any intellectual property or product marketing rights of any other person or entity;

(vii) it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and any Project Agreement and that during the term of this Agreement and any Project Agreement, it will not enter into any agreement which would in any way prevent or restrict inVentiv from performing the Services under this Agreement; and

(viii) it is solely responsible for reviewing and approving Client's product promotional materials and literature and for ensuring all such materials comply with Applicable Law; and

(ix) Client shall notify inVentiv in the event it is subject to or becomes subject to a Federally Mandated Corporate Integrity Agreement (CIA) or other compliance obligations which require inVentiv to provide Client with data, training, analysis, oversight or certifications that are not contemplated by the Services described herein. In such event, the Parties shall mutually agree on an appropriate allocation of costs and expenses associated with inVentiv's provision of such CIA related data, training, analysis, oversight or certifications not included in the scope of Services provided under this Agreement or any related Project Agreement.

4. Independent Contractors; inVentiv Personnel

(a) inVentiv and its directors, officers, employees and any persons providing services under the Agreement and any Project Agreement are at all times independent contractors with respect to Client. Persons provided by inVentiv to perform Services shall not be deemed employees of Client. Neither this Agreement nor the Services to be rendered hereunder shall for any purpose whatsoever or in any way or manner create any employer-employee relationship between inVentiv, its directors, officers, employees and any persons providing Services under the Agreement and Client. Client understands that inVentiv may utilize independent contractors in connection with its performance of the Services. inVentiv will be primarily responsible and fully liable for the performance of such independent contractors, including without limitation any breach of this Agreement (including any Project Agreement) by an independent contractor.

(b) inVentiv is, and at all times shall remain, solely responsible for the human resource and performance management functions of all inVentiv personnel provided to perform the Services. inVentiv shall be solely responsible and liable for all disciplinary, probationary and termination actions taken by it, and for the formulation, content and dissemination of all employment policies and rules (including written disciplinary, probationary and termination policies) applicable to its employees, agents and contractors (individually, an "inVentiv Employee" and collectively, "inVentiv Employees").

(c) inVentiv shall obtain and maintain worker's compensation insurance and other insurances required for inVentiv Employees performing the Services and acknowledges that

4.

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Client does not, and shall not obtain or maintain such insurances, all of which shall be inVentiv's sole responsibility.

(d) Except as otherwise set out in this Agreement or in a Project Agreement, Client shall have no responsibility to inVentiv or any inVentiv Employee for any compensation, expense reimbursements or benefits (including, without limitation, vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits and disability benefits), payroll-related or withholding taxes, or any governmental charges or benefits (including, without limitation, unemployment and disability insurance contributions or benefits and workers compensation contributions or benefits) that may be imposed upon or be related to the performance by inVentiv or its employees, agents or contractors of the obligations under this Agreement or any Project Agreement, all of which shall be the sole responsibility of inVentiv. To clarify, Client will not withhold any income tax or payroll tax of any kind on behalf of inVentiv.

(e) Any request by Client for removal of an inVentiv Employee assigned to provide Service(s) shall be made in writing, supported by the Client's reasons for requesting the removal and documentation of the inVentiv Employee's actions and/or behavior that support the request. Following any such request and subject to inVentiv's internal human resource policies, the inVentiv Employee will be removed from providing Services to Client. In addition, all employment decisions regarding an inVentiv Employee shall be made solely and exclusively by inVentiv and are subject to compliance at all times with inVentiv's human resource policies and procedures. For the avoidance of doubt this means, by way of example, that inVentiv may in its exclusive discretion determine whether to retain, reassign, or dismiss an inVentiv Employee who has been removed at Client's request and in compliance with inVentiv's internal human resource policy.

5. inVentiv Compensation

(a) In consideration of the performance of the Services, Client shall pay inVentiv the fees, costs and expenses (collectively, the "Fees") as set forth in each Project Agreement. inVentiv shall bill Client as set forth in each Project Agreement and invoices shall be sent by inVentiv to Client on a monthly basis for the Fees for Services.

(b) In addition to the Fees set forth in a Project Agreement, certain necessary and reasonable expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost incurred by inVentiv. Pass-through costs specific to a particular Service shall be set forth in the Project Agreement.

(c) Payments are due within [*] following Client's receipt of each applicable invoice from inVentiv. If an invoice is not paid within this [*] period, inVentiv reserves the right to impose a [*] on all amounts not paid when due, provided that Client may withhold any portion of an amount invoiced that is the subject of a good faith dispute pending resolution of the dispute, and no [*] may be imposed during the pendency of any such good faith dispute.

5.

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(d) In the event Client will be issuing purchase orders for payment of inVentiv invoices, Client shall issue such purchase orders in a timely manner in accordance with the terms and conditions set forth herein. The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Agreement provides the terms and conditions governing the relationship between the Parties.

6. Confidentiality

(a) During, the performance of the Services contemplated by this Agreement, each Party may learn confidential, proprietary, and/or trade secret information of the other Party (“Confidential Information”). The Party disclosing Confidential Information shall be referred to as the “Disclosing Party” and the Party receiving Confidential Information shall be referred to as the “Receiving Party.”

(b) Confidential Information means, any information, unknown to the general public, which is disclosed or created by the Disclosing Party to the Receiving Party under this Agreement. Confidential Information includes, without limitation, the terms set forth in this Agreement, technical, trade secret, commercial and financial information about either Party’s (i) research or development; (ii) marketing plans or techniques, contacts or customers; (iii) organization or operations; (iv) business development plans (i.e., licensing, supply, acquisitions, divestitures or combined marketing); (v) products, licenses, trademarks, patents, other types of intellectual property or any other contractual rights or interests (including without limitation processes, procedures and business practices involving trade secrets or special know-how), (vi) pricing and financial information, and (vii) the names and contact information (i.e., phone number, address and e-mail address) of each Party’s employees, consultants, investigators, and service providers. The Receiving Party shall neither use nor disclose Confidential Information received from the Disclosing Party for any purpose other than as specifically allowed by this Agreement.

(c) Upon the expiration or termination of this Agreement and receipt of Disclosing Party’s written request, Receiving Party, at its option, shall promptly either (a) return to the Disclosing Party all tangible forms of Confidential Information in its possession, including any and all copies and/or derivatives of Confidential information made by either Party or their employees as well as any writings, drawings, specifications, manuals or other printed or electronically stored material based on or derived from, Confidential Information, (b) destroy Confidential Information in its possession and deliver to Disclosing Party a certification that such destruction has occurred; provided however, that Receiving Party may retain a copy of any information, including Confidential Information, that the Receiving Party reasonably believes is required to comply with applicable laws or regulations or to effectuate the Purposes of this Agreement. The Receiving Party shall not disclose, to third parties any Confidential Information or any reports, recommendations, conclusions or other results of work under this Agreement without prior consent of an officer of the Disclosing Party. The obligations set forth in this Section 6, including the obligations of confidentiality and non-use, shall be continuing and shall survive the expiration or termination of this Agreement and the Project Agreement and will continue for a period of [*] front the date of such expiration or termination.

6.

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(d) The obligations of confidentiality and non-use set forth herein shall not apply to the following: (i) Confidential Information at or after such time that it is or becomes publicly available through no fault of the Receiving Party; (ii) Confidential Information that is already independently known to the Receiving Party as shown by prior written records; (iii) Confidential Information at or after such time that it is disclosed to the Receiving Party by a third party with the legal right to do so; and (iv) solely with respect to the specific relevant process, order or request, Confidential Information required to be disclosed pursuant to judicial process, court order or administrative request, provided that the Receiving Party shall so notify the Disclosing Party sufficiently prior to disclosing such Confidential Information as to permit the Disclosing Party to seek a protective order or similar order limiting or restraining the disclosure.

7. Restrictions on Solicitation

(a) Neither Party may solicit the employees or independent contractors of the other Party that are directly involved with the services contemplated by this Agreement or the applicable Project Agreement to become employees of or consultants to, the soliciting Party during the Term of this Agreement and any Project Agreement and for [*] period following the termination of both this Agreement and any Project Agreement. The provisions of this Section 7 shall not apply with respect to employees or independent contractors of either Party who seek employment from the other Party on their own initiative, such as, but not limited to, in response to a Party's general vacancy announcement or advertisement.

(b) Client agrees during the Term of this Agreement and for [*] hereafter that it will not knowingly and deliberately: (i) provide any contact information (including name, address, phone number or e-mail address) of any inVentiv Employee to any third party which provides or proposes to provide Client with the same services being provided by inVentiv pursuant to a Project Agreement, or (ii) assist actively in any other way such a third party in employing or retaining such inVentiv Employee.

(c) Each Party shall pay to the other, or in the case of the foregoing Section 7(b) Client shall pay to inVentiv or cause the third party to pay to inVentiv, as the ease may be, [*] for each employee so employed or retained as liquidated damages for breach of Sections 7(a) or 7(b).

8. Indemnification

(a) inVentiv shall indemnify and hold Client, its officers, directors and employees harmless from and defend them against any and all third party liabilities, losses, proceedings, suits, actions, damages, claims or expenses of any kind, including court costs and reasonable attorneys' fees (collectively, "Losses") which are caused by: (i) any negligent acts or omissions by or the willful misconduct of inVentiv, its directors, officers or inVentiv Employees, and (ii) any material breach of this Agreement, any Project Agreement, or Applicable Law by inVentiv, its directors, officers or inVentiv Employees.

(b) Client shall indemnify and hold inVentiv, its officers, directors and employees harmless from and defend them against any and all Losses which are caused by: (i) any negligent

7.

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acts or omissions by or the willful misconduct of Client, its directors, officers or employees, (ii) any material breach of this Agreement, any Project Agreement, or Applicable Law by Client, its directors, officers or employees, (iii) any product liability claims, whether arising out of warranty, negligence, strict liability (including manufacturing, design, warning or instruction claims) or any other product based statutory claim, and (iv) any intellectual property infringement claims relating to any trademarks owned by or licensed to Client.

(c) The foregoing indemnity obligations of each Party will not apply to Losses against which the other Party is required to indemnify. In case any action, proceeding or claim shall be brought against one of the Parties hereto (an "Indemnified Party") based upon any of the above claims and in respect of which indemnity may be sought against the other Party hereto (the "Indemnifying Party") such Indemnified Party shall promptly notify the Indemnifying Party in writing. The failure by an Indemnified Party to notify the Indemnifying Party of such Claim shall not relieve the Indemnifying Party of responsibility under this Section, except to the extent such failure adversely prejudices the ability of the Indemnifying Party to defend such claim. The Indemnifying Party at its expense, with counsel of its own choice, shall defend against, negotiate, settle or otherwise deal with any such claim, provided that the Indemnifying Party shall not enter into any settlement or compromise of any claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party without the Indemnified Party's prior written consent, which will not be unreasonably withheld. The Indemnified Party may participate in the defense of any claim with counsel of its own choice and at its own expense. The Parties agree to cooperate fully with each other in connection with the defense, negotiation or settlement of any such claims. In the event that the Indemnifying Party does not undertake the defense, compromise or settlement of any claim, the Indemnified Party shall have the right to control the defense, or settlement of such claim with counsel of its choosing.

(d) Client shall reimburse inVentiv for all reasonable actual out-of-pocket expenses incurred by inVentiv in connection with responses to subpoenas and other similar legal orders issued to inVentiv in respect to Client's product or the Services performed under this Agreement and the applicable Project Agreement. However, Client shall have no obligation to reimburse inVentiv for any such expenses (and to the extent paid by Client to inVentiv, shall be repaid by inVentiv to Client) arising out of, in connection with or otherwise relating to actions or omissions of inVentiv or its employees, officers, directors and/or affiliates that violate this Agreement or Applicable Law.

9. Limitation of Liability

Neither Party shall be liable to the other Party with respect to any subject matter of this Agreement or any Project Agreement under any contract, tort, negligence, strict liability, breach of warranty (express or implied) or other theory for any indirect, incidental, special, punitive, exemplary or consequential damages, nor for any loss of revenues or loss of profits, even if advised of the possibility of such damages. In addition, the total liability of inVentiv to Client resulting from the performance of the services set forth in this Agreement and in any one or more Project Agreements between the Parties shall be limited to [*].

8.

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10. Intellectual Property; Ownership

(a) Except as Set forth in Sections 10(b) below, all documents, materials, reports and deliverables provided by inVentiv to Client pursuant hereto whether or not patentable, copyrightable, or susceptible to any other form of legal protection which are made, conceived, reduced to practice or authored by inVentiv, or inVentiv's employees, representatives or agents (if any) as a result of the performance of Services, or which are derived from use or possession of Client's Confidential Information (collectively, the "Deliverables") shall be the sole and exclusive property of Client. Each Deliverable constituting an original work shall be considered a work made for hire under applicable copyright laws. Subject to Section 10(b) below, inVentiv hereby assigns and agrees to assign to Client all right, title and interest in all worldwide intellectual property rights in the Deliverables, including without limitation, patents, copyrights, and trade secrets.

(b) Notwithstanding anything to the contrary set forth herein, to the extent any Deliverable or work made for hire include inVentiv's concepts, ideas, models, know-how, software, methodologies, technology, techniques, procedures, management tools, workshops, manuals, macros, data files, inventions, and other intellectual capital and property that inVentiv has developed, created or acquired prior to or materially independent of performing Services under this Agreement as can be demonstrated by competent proof (the "inVentiv Materials"), inVentiv shall retain exclusive ownership in such inVentiv Materials, inVentiv hereby grants Client a perpetual, non-exclusive, non-transferable, royalty-free right and license, for it to use the inVentiv Materials solely in connection with its use of the Deliverables created by inVentiv in connection with the Services.

11. Term

The Agreement shall be in effect as of the Effective Date and shall remain in effect until the third anniversary of the Effective Date (the "Term") or until such later date as may be set forth in a Project Agreement (it being understood that this Agreement will not terminate in the event the term set forth in a Project Agreement is longer than the term set forth herein). The Parties may extend this Agreement for additional periods of one year each (each an "Additional Term") by mutual written agreement not less than thirty (30) days prior to the end of the then current term.

12. Termination

(a) This Agreement and any Project Agreement may be terminated by inVentiv or Client upon giving written notice as follows:

(i) by inVentiv, if any undisputed payment to inVentiv by Client is not made when due and such payment is not made within [*] from the date of written notice from inVentiv to Client of such nonpayment;

(ii) unless otherwise agreed in a Project Agreement, by Client for any reason or no reason upon [*] written notice to inVentiv specifying the effective date of termination;

9.

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(iii) by either Party, in the event that the other Party has committed a material breach of this Agreement and such breach has not been cured within [*] of receipt of written notice from the non-breaching Party of such breach (provided that, during the thirty (30) day cure period for termination due to breach. Each Party will continue to perform its obligations under the Agreement);

(iv) by either Party, in the event the other Party is either debarred from federal contracting or is a “Sanctioned Entity”. For purposes hereof, a Sanctioned Entity is an entity that:

(A) Is currently under indictment or prosecution for, or has been convicted (as defined in 42 C.F.R. § 1001.2) of: (1) any offense related to the delivery of an item or service under the Medicare or Medicaid programs or any program funded under Title V or Title XX of the Social Security Act (the Maternal and Child Health Services Program or the Block grants to States for Social Services programs, respectively), (2) a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service, (3) fraud, theft, embezzlement or other financial misconduct in connection with the delivery of a health care item or service, (4) obstructing an investigation of any crime referred to in (1) through (3) above, or (5) unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; or

(B) Has been required to pay any civil monetary penalty regarding false, fraudulent, or impermissible claims under, or payments to induce a reduction or limitation of health care services to beneficiaries of, any state or federal health care program, or is currently the subject of any investigation or proceeding which may result in such payment; or

(C) Has been excluded from participation in the Medicare, Medicaid, or Maternal and Child Health Services (Title V) program, or any program funded under the Block Grants to States for Social Services (Title II) program; or

(v) by either Party, in the event that the other Party has become insolvent or has been dissolved or liquidated, filed or has filed against it, a petition in bankruptcy and such petition is not dismissed within thirty (30) days of the filing, makes a general assignment for the benefit of creditors; or has a receiver appointed for a substantial portion of its assets.

(b) Upon the effective date, of such termination, the Parties shall have no further obligation to each other (other than those set forth in Sections 4, 6, 7, 8, 9, 10 and 13), except that (i) upon Client’s request, inVentiv shall undertake reasonable efforts to provide for the orderly wind-up and transition of the Services to Client and (ii) Client shall pay the amounts set forth or provided for in any Project Agreement through the actual date of termination, as well as any non-cancellable costs incurred. Where a Project Agreement provides for fixed fees or progressive payments for Services performed, the fees shall be paid pro rata in accordance with the work performed, and any overpayments shall be promptly returned to Client.

13. Venue and Jurisdiction

This Agreement shall be construed according to the laws of the State of New Jersey (without reference to any principles regarding conflicts of law) and any action brought by either

inVentiv or Client in connection with this Agreement shall be brought in the state or federal courts located in the State of New Jersey.

14. Miscellaneous

(a) Each Party undertakes to maintain, as applicable, General Liability insurance of [*] per occurrence/[*] annual aggregate, Workers' Compensation Statutory, Employer's Liability insurance of [*], Automobile Liability insurance of [*] combined single limit each occurrence, Products/Completed Operations and, with respect to inVentiv only, Professional Errors and Omissions Liability insurance of [*] per occurrence/[*] annual aggregate. Limits may be provided with Umbrella Excess insurance. Insurance companies must have an AM Best Rating of "A-/VII" or better, or an analogous rating by a similar organization if the insurance company is not a United States company. In addition, Client shall carry product liability insurance in the amount of at least [*]. Neither Client's nor inVentiv's indemnity shall be capped by its insurance limits. Each Party shall name the other Party as an additional insured on all liability insurance coverage as their interests may appear. In addition, within ten (10) days of execution of this Agreement, Client will provide inVentiv with evidence of coverage complying with this Section 14. The Parties understand and agree that additional insurance requirements may be set forth in the Project Agreements.

(b) Neither inVentiv nor Client may assign or transfer this Agreement or any Project Agreement or any of its rights, duties or obligations hereunder without the other Party's prior written consent; provided, however, that either inVentiv or Client may assign or transfer its rights, duties and obligations as part of an acquisition or purchase, without the prior written consent of the other Party when: (i) such assignment is to a successor-in-interest to all or substantially all of the ownerships interest or business assets of such Party or such Party's division or product line for which the Services are provided, whether in a merger, sale of stock, sale of assets, license, or other similar transaction; and (ii) the successor is a financially capable business entity. Any permitted successor or assignee of this Agreement and the rights and/or obligations hereunder, will in writing (reasonably satisfactory in form and substance) to the other Party, expressly assume this Agreement and any existing Project Agreement and the rights and obligations hereunder. If such a writing is not received, any proposed assignment or transfer need not be recognized and shall be null and void.

(c) This Agreement supersedes all prior arrangements and understandings between the Parties related to the subject matter hereof.

(d) Except for Client's payment obligations, noncompliance with the obligations of this Agreement due to a state of force majeure, the laws or regulations of any government, regulatory or judicial authority, war, civil commotion, destruction of facilities and materials, fire, flood, earthquake or storm, shortage of materials, failure of public utilities or common carriers, and any other similar causes beyond the reasonable control of the applicable Party, shall not constitute a breach of contract.

(e) If any provision of this Agreement is finally declared or found to be illegal or unenforceable by a court of competent jurisdiction, both Parties shall be relieved of all

obligations arising under such provision, but, if capable of performance, the remainder of this Agreement shall not be affected by such declaration or finding.

(f) This Agreement, together with each applicable Project Agreement (including any attachments or exhibits hereunder or thereunder), contains all of the terms and conditions of the agreement between the Parties and constitutes the complete understanding of the Parties with respect thereto. No modification, extension or release from any provision hereof shall be affected by mutual agreement, acknowledgment, acceptance of contract documents, or otherwise, unless the same shall be in writing signed by the other Party and specifically described as an amendment or extension of this Agreement.

(g) The form and content deny public announcement to be made by one Party regarding this Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other Party (which consent may not be unreasonably withheld), except as may be required by applicable law, in which event the other Party shall endeavor to give the other Party reasonable advance notice and review of any such disclosure. Notwithstanding the above, either Party may, in connection with its general marketing materials and without the consent of the other Party, list the name of the other Party in a non-descriptive fashion, in a list of the names of other similarly situated third parties that such Party does business with.

(h) This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

(i) Any notices required or permitted under this Agreement shall be given in person or sent by first class, certified mail to:

To Client: Address: Dynavax Technologies Corporation 2929 Seventh Street, Suite 100 Berkeley, CA 94710	To inVentiv Address: inVentiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873
Attention: Senior Product Director Fax: 510-848-1327	Attention: President Fax: 732-537-4999
Copy To: General Counsel Dynavax Technologies Corporation 2929 Seventh Street, Suite 100 Berkeley, CA 94710	Copy To: inVentiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873 Attn: VCS General Counsel

or to such other address or to such other person as may be designated by written notice given from time to time during the term of this Agreement by one Party to the other.

(j) Each of the Parties shall do, execute and perform and shall procure to be done and perform all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.

(k) Except as otherwise expressly provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the Consummation of the transactions contemplated by this Agreement or each Project Agreement.

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

**DYNAVAX TECHNOLOGIES
CORPORATION**

INVENTIV COMMERCIAL SERVICES, LLC

By: /s/Ryan Spencer

By: /s/Theodore Wong

Title: Sr. Director, Heplisav.B

Title: VP & CFO

14.

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FORM OF PROJECT AGREEMENT

This Project Agreement (the "Project Agreement") made as of _____, 20__ by and between INVENTIV COMMERCIAL SERVICES, LLC, with its principal office located at 500 Atrium Drive, Somerset, New Jersey 08873 ("inVentiv") and DYNVAVX TECHNOLOGIES CORPORATION, with its principal office located at 2929 Seventh Street, Suite 100, Berkeley, CA 94710 ("Client"). Client and inVentiv may each be referred to herein as a "Party" and collectively, the "Parties".

RECITALS

- A. Client and inVentiv have entered into a Master Services Agreement dated as of January 11, 2016 (the "Agreement").
B. Client and inVentiv desire to enter into this Project Agreement (the "PA").

1. Interpretation and Construction

(a) The Parties confirm that the Master Service Agreement shall govern the relationship between the Parties. Unless otherwise specifically set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the Master Service Agreement and the terms and conditions set forth in this Project Agreement, the terms and conditions set forth in the Master Service Agreement shall take precedence, govern and control.

(b) The Parties hereby acknowledge that the terms set forth in this Master Service Agreement are incorporated herein by reference, as if fully set forth at length therein.

2. The Services

A detailed description of the services (the "Services") is set forth on Exhibit A attached hereto.

3. Fees

Set forth on Exhibit B attached hereto is a summary of the costs and fees to be paid by Client to inVentiv for the performance of the Services.

WHEREFORE, the Parties hereto have caused this Project Agreement to be executed by their duly authorized representatives.

DYNVAVX TECHNOLOGIES CORPORATION

INVENTIV COMMERCIAL SERVICES, LLC

By: _____

By: _____

Title: _____

Title: _____

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EXHIBIT A
THE SERVICES

16.

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EXHIBIT B
FEES AND COSTS

17.

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**PROJECT AGREEMENT
(DETAILING)**

This Project Agreement (this “Project Agreement”) is made as of October 31, 2017 (the “Effective Date”) by and between inVentiv Commercial Services, LLC with an office located at 500 Atrium Drive, Somerset, NJ 08873 (“inVentiv”) and Dynavax Technologies Corporation with an office located at 2929 Seventh Street, Suite 100, Berkeley, CA 94710 (“Client”). Client and inVentiv may each be referred to herein as a “Party” and collectively, the “Parties”.

RECITALS

- A. Client and inVentiv have entered into a Master Service Agreement dated as of January 11, 2016 (the “MSA”).
- B. Client and inVentiv desire to enter into this Project Agreement pursuant to which inVentiv shall provide a field force of inVentiv account managers to provide detailing services as set forth more fully in Exhibit A attached hereto.

1. Interpretation and Construction

(a) The Parties confirm that the MSA shall govern the relationship between the Parties. Unless otherwise specifically set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the MSA and the terms and conditions set forth in this Project Agreement, the terms and conditions set forth in the MSA shall take precedence, govern and control, except to the extent that a term in the Project Agreement expressly states that it supersedes the terms of the MSA.

(b) The Parties hereby acknowledge that the terms set forth in the MSA are incorporated herein by reference, as if fully set forth at length therein.

2. The Services

A description of the detailing services (the “Detailing Services”) is set forth on Exhibit A attached hereto and made a part hereof. A description of sales operations, implementation and on-going services (the “Sales Operations Services”) is set forth on Exhibit B attached hereto and made a part hereof. A description of the compliance services (the “Compliance Services”) is set forth on Exhibit C attached hereto and made a part hereof. A description of the training services (the “Training Services”) is set forth on Exhibit D attached hereto and made a part hereof (the Training Services, Compliance Services, Sales Operations Services and, collectively with the Detailing Services, the “Services”).

3. The Term

This Project Agreement shall be in effect as of the Effective Date and shall remain in effect until the second anniversary of the Deployment Date (as defined in Exhibit A), unless

extended as provided herein (the "Term"). The period from the Effective Date until the one year anniversary of the Deployment Date shall be referred to herein as "Year One" and the period from the one year anniversary of the Deployment Date through the day prior to the second anniversary of the Deployment Date shall be referred to herein as "Year Two". The Term may be extended for additional periods of one (1) year (each an "Additional Term") upon the mutual written agreement of the Parties not less than [*] before the end of the Term or any Additional Term.

4. Termination

(a) Either Party may terminate this Project Agreement in accordance with Section 12 of the MSA.

(b) After the Deployment Date, Client may terminate this Project Agreement in accordance with Section 12(a)(ii) of the MSA; provided, however, that in the event the actual termination date occurs [*], Client shall pay inVentiv a termination fee as set forth in the following table:

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

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

(c) In the case of termination of this Project Agreement by Client (except for termination by Client pursuant to Section 12(a) (ii)(iii) or (iv) of the MSA), at the end of the Term (or any Additional Term), or in the event of a Block Conversion, Client shall (in addition to all other payment obligations under this Agreement) promptly pay (or if paid by inVentiv, promptly reimburse) inVentiv for: the amount due any lessor or rental agent of the equipment leased or owned by inVentiv and provided to members of the Project Team (i.e., fleet automobiles, laptops and iPads) (collectively, the “Equipment”), for any early termination of the lease or rental agreement. In addition, Client may elect to either: (i) in the event the Equipment is owned by inVentiv, transfer the Equipment to Client and pay an amount equal to the net book value (if any) of the Equipment on the books of inVentiv at the time of the transfer event, or in the event the Equipment is subject to a lease or finance lease, the Equipment may be transferred to Client (subject to the last sentence of this Section 4 (c)) and Client shall assume the responsibility for all further payments due (including costs associated with the transfer), or (ii) pay inVentiv the net loss to inVentiv on such Equipment determined by the difference between the net book value of such Equipment and the actual net price received by inVentiv for the disposal of such Equipment, plus any amounts due by inVentiv in connection with the lease or rental termination and costs associated with the storage and disposal of said Equipment. Any proposed transfer of Equipment to Client shall be subject to Client establishing its own relationship and credit with the entity that inVentiv contracted with to lease or rent such Equipment.

(d) [*].

(e) In the event of termination, Section 12(b) of the MSA shall apply.

5. **Conversion (Selective Hiring and Block Conversion)**

(a) Notwithstanding Section 7 of the MSA, during the Term (or any Additional Term) and after the Hire Date, Client may solicit, employ or retain one or more of the Account Managers (as defined in Exhibit A) or RBDs (as defined in Exhibit A) performing Services hereunder (a “Selective Hiring”). Client shall give [*] prior written notice to inVentiv of Selective Hiring. Should there be Selective Hiring by Client, inVentiv will backfill the position to perform the Services hereunder. In the event Client wishes to implement a Selective Hiring during the Term (or any Additional Term), Client shall pay inVentiv [*] per inVentiv Account Manager and [*] per RBD as a recruitment fee for replacement/backfill.

(b) Notwithstanding Section 7 of the MSA, Client may solicit, employ or retain the inVentiv Account Managers performing Services hereunder and inVentiv shall not backfill the respective position (a “Block Conversion”) after the Deployment Date; provided, however, that Client provides at least [*] prior written notice to inVentiv of any Block Conversion. In the event Client wishes to implement a Block Conversion, Client shall pay inVentiv a Conversion fee based upon the date of the actual Block Conversion, in accordance with the following:

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

In the event Client wishes to perform a Block Conversion prior to the [*], Client shall pay, in addition to any Block Conversions Fees outlined above, a scale down fee according to the following table:

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

inVentiv shall also reduce the Fixed Monthly Fee (as defined in Exhibit E, Section I(b)) and the annual Incentive Fee (as defined in Exhibit E, Section III(b)), for each Account Manager converted pursuant to the Block Conversion allowance according to the following tables:

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

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

The above reduction amounts shall be prorated based on the actual date of such Block Conversion.

(c) Client understands and agrees that inVentiv cannot guarantee that the Account Managers will agree to participate in a Selective Hiring or Block Conversion.

(d) In the event Client implements a Selective Hiring or Block Conversion, the Parties agree that any and all training materials created by inVentiv that are inVentiv Material under Section 10(b) of the MSA and made available to the Account Managers will be immediately returned to inVentiv by the applicable Account Manager and/or Client, as applicable, it being understood and agreed that the inVentiv Materials constitute valuable and proprietary information of inVentiv and is subject to the confidentiality obligations set forth in Section 6 of the MSA. Within [*] of implementing a Selective Hiring or Block Conversion, Client shall return to inVentiv any originals and copies of inVentiv Materials in Client’s possession pertaining to the person(s) who are the subject of the hiring by Client.

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

(e) In the event Client conducts a Selective Hiring or Block Conversion (collectively, a “Conversion”) and the converted Account Managers had been provided with use of a fleet automobile leased, rented or owned by inVentiv and Client wishes to commence an arrangement with the fleet vendor to assume such cars (and all associated costs and liabilities) under Client’s name, the converted Account Managers may only to continue to have access to such automobile following the Conversion if Client either: (i) registers the fleet automobile under its name; or (ii) ensures that inVentiv remains named as an additional insured under Client’s automobile insurance policies until such time as the vehicle is registered in Client’s name ([*]). The Parties understand and agree that it is solely Client’s obligation to ensure one of the above actions are taken and Client shall be responsible for indemnifying, defending and holding inVentiv harmless for all damages resulting from Client’s failure to take such action. The Parties further agree that on the effective date of the Conversion, Client shall destroy the inVentiv insurance card(s) in the fleet vehicle(s) of the converted Account Managers.

6. Fees

Set forth on Exhibit E are the costs and fees to be paid by Client to inVentiv for the performance of the Services.

WHEREFORE, the parties hereto have caused this Project Agreement to be executed by their duly authorized representatives on the day and year first above written.

**DYNAVAX TECHNOLOGIES
CORPORATION**

By: /s/Ryan Spencer

Name: Ryan Spencer

Title: VP, Corporate Strategy

Date: 11-6-2017

**INVENTIV COMMERCIAL
SERVICES, LLC**

By: /s/Theodore Wong

Name: Theodore Wong

Title: VP & CFO

Date: Nov 8, 2017

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EXHIBIT A
THE DETAILING SERVICES

inVentiv will provide Client with a field force that shall consist of [*] account managers (the “ inVentiv Account Managers” or “Account Managers”) who shall detail Client’s Product by making Calls pursuant to a Call Plan on Targets. inVentiv shall also provide [*] regional business directors (“RBDs”) who shall manage the inVentiv Account Managers, as well as work to gain access of the Product by presenting the value proposition and: (i) developing and implementing a business plan to gain access, such plan to be reviewed and approved by Client prior to its use; (ii) achieving formulary and protocol coverage; and (iii) working with the inVentiv Account Managers to handle access issues. In addition, inVentiv shall provide [*] national business director (“NBD” and, collectively with inVentiv Account Managers, and RBDs, the “Project Team”).

In the event that the Parties desire to increase the type and / or number of Project Team members providing Services under this Project Agreement they may do so by utilizing a Project Team Member Request Form (the “Request Form”) in a format that is substantially similar to the one attached hereto as Exhibit A – 1. The details set forth in the Request Form shall be mutually agreed upon by the Parties. For clarification, the Request Form may not be used in those situations where it is the intent of the Parties to amend terms and conditions of this Project Agreement other than those specific items set forth on the Request Form.

In connection with the promotion of Client’s Product, inVentiv shall provide the Client with following services set forth in this Exhibit A (collectively, the “Services”).

I. ADDITIONAL DEFINED TERMS

(a) “Call” means the activity undertaken by an Account Manager to detail the Product, further described as a face-to-face presentation by an Account Manager to a Target and will include providing the Target with Product Literature (as directed by Client).

(b) “Call Plan” means a plan jointly designed by Client and inVentiv, which is intended to enhance the efficiency and effectiveness of the inVentiv Account Managers in making Calls. The Call Plan will be maintained by inVentiv at its offices with a copy of such Call Plan maintained by Client at its offices, and may be amended or reconfigured from time to time solely at Client’s written request, with Client paying inVentiv a fee, to be agreed upon in writing, for the performance of such amendment or reconfiguration services.

(c) “Deployment Date” means the date of the first Call by an inVentiv Account Manager, which is anticipated by the Parties to be on or about [*]. Notwithstanding the date set forth herein, the Deployment Date will be the actual date of the first Call by an inVentiv Account Manager.

(d) “Healthcare Professional” or “HCP” means a person, other than an individual patient, including, without limitation, any medical or health care professional or entity in a position to purchase, lease, recommend, use, influence or arrange for the purchase or lease of, or

prescribe the Products with whom Agents come in contact with in connection with providing the Services hereunder.

(e) "Hire Date" means the date the first inVentiv Account Manager is assigned to the Project Team.

(f) "Product" shall mean HEPLISAV-B.

(g) "Product Literature" shall mean promotional, informative and other written information concerning the Product. All Product Literature shall be prepared and provided by Client. The inVentiv Account Managers shall utilize the Product Literature when making Calls and shall not use any other documentation to promote the Product.

(h) "inVentiv Account Manager" means an individual provided by inVentiv who is engaged under this Agreement to detail the Products.

(i) "Targets" means the licensed practitioners who are identified by Client as potential prescription writers and/or customers for the Product as provided by Client to inVentiv. Targets also include Integrated Delivery Networks (IDNs)/Health Systems, Accountable Care Organizations (ACOs), including Medicare ACOs, State Public Health Departments, Corporate Accounts, hospitals, and other Key Account Customers that are identified by Client and provided by Client to inVentiv.

II. HIRE STATUS, FLEET, TRAINING AND MEETINGS

(a) Hire Status—Generally. Upon execution of this Project Agreement, inVentiv will commence recruiting and hiring activities for the inVentiv Account Managers. In the event that inVentiv receives notification to commence recruiting and hiring activities with respect to a position or territory, and that position or territory is subsequently cancelled by Client at any time after [*] from the date of such notification, then Client shall pay a cancellation fee to inVentiv in the amount of [*] for each such cancelled position or territory.

(b) Hire Status—Provisioning. inVentiv shall provide the inVentiv Account Managers with the following:

(i) Salary, benefits, and bonus as agreed by Client.

(ii) Fleet automobiles and fleet management services to include the following:

(1) Coordination of department of motor vehicle ("RBDV") checks and confirmation of completion for all employees in fleet vehicles

(2) Management of vendor involvement for accidents, fuel cards, and insurance

- (3) Coordination of delivery of bridge rentals or fleet vehicles dependent upon background and RBDV check completion, timeline of deployment and vehicle availability
- (4) Recommendations for snow belt vehicles as applicable for project
- (5) Ordering new vehicles or transfer of existing surplus vehicles dependent upon team size, availability and Client budget
- (6) Timely pick-up of fleet vehicles through third-party vendor for terminations and leaves of absence (“LOAs”) as appropriate

(iii) The above stated fleet management services shall be managed by an inVentiv Fleet Analyst and assumes the following:

- (1) Timely notification of territory and district locations for vehicle placement
- (2) 8-week standard timeline for ordering of new vehicles
- (3) Vehicles delivered upon first day of field deployment

(iv) Human resources management services to include the following:

- (1) Creation, distribution, and tracking of offer letters and new hire checklist items
- (2) Distribution of emails from Sterling InfoSystems to complete required data for background screening and drug screen
- (3) Distribution of info regarding the new hire green site to acknowledge reference documents, print new hire forms and send to human resources
- (4) Tracking of background and drug screening results from Sterling InfoSystems (follow-up may be required)
- (5) Notification to Client of background issues
- (6) Conduct new hire orientation Webex on first day of employment or live at training
- (7) Works with NBD/Project Lead for instances of PIP letters, investigations of compliance and other issues
- (8) Coordination with leave administration on all state and federal leaves of absences

(9) downsizing and conversions

Delivery of termination notices, participation in personnel calls regarding

(v) The above stated human resources management services shall be managed by an inVentiv HR Manager and assumes the following:

(1) hires Timely completion of Sterling InfoSystems background link from new

(2) inclusion in the offer letters Information regarding vacation, bonus, expectations are available for

(vi) Information technology hardware to include iPads and laptop computers (including sales force automation software) and printers.

(vii) CRM and operational support as further described in Exhibit B.

(c) Training - The training responsibilities of the Parties are as follows:

(i) inVentiv shall be responsible for training members of the Project Team further described in Exhibit D.

(ii) Client shall be responsible for training members of the Project Team concerning all Product specific information including Product complaint handling procedures, applicable specific Client health care compliance policies and Client customer service policies and procedures, orientation to Client's business, and adverse event reporting policies and procedures. The Parties agree to work together to mutually determine if, when, and at what cost additional training shall be provided to members of the Project Team.

(d) All expenses associated with POA meetings and national training meetings shall be paid for by Client as a pass-through expense or direct billed to Client.

III. PERFORMANCE

If Client believes in good faith that the performance of any inVentiv Account Manager is unsatisfactory or is not in compliance with the provisions of this Agreement, Client shall notify inVentiv and inVentiv shall promptly address the performance or conduct of such person in accordance with its internal human resource policies; provided however, if removal is requested by Client, Client shall notify inVentiv in writing of the basis for such requested removal and the inVentiv Account Manager will not return to servicing Client under this Agreement without Client's prior consent. In the event that Client determines in good faith that an inVentiv Account Manager has violated any applicable law, regulation or policy, Client shall notify inVentiv (in writing). inVentiv shall promptly address the issue and take all reasonable and appropriate action (including but not limited to termination of such employee). No such action shall be contrary to inVentiv's internal human resource policies and procedures.

IV. CALLS AND TARGETS

The inVentiv Account Managers shall provide Product Literature and Product samples (as needed) when making Calls as directed by Client. Client is solely responsible for the content, production and distribution (to the inVentiv Account Managers) of the Product Literature. Each inVentiv Account Manager shall record information concerning each Call, including but not limited to Product sample distribution, and concerning the profile of each individual Target (or other physician called upon) on whom the inVentiv Account Manager calls. Client shall permit inVentiv to access and use all Target, sales and Call-related data that supports or is associated with the Services that are performed in accordance with this Agreement (the "Data"). The Data shall be used by inVentiv for the purpose of evaluating the performance of its Project Team members; and, provided that inVentiv de-identifies all Client and Product specific components of the Data, including removing the name and other personal information of HCPs provided by Client to, or otherwise learned by, inVentiv in connection with its work under this Agreement, for business development and analytics purposes.

V. THE PRODUCTS

The Product shall be promoted by inVentiv under trademarks owned by or licensed to Client and are Products which Client has all lawful authority necessary to market and sell the Products in all geographic areas where the Products are to be promoted under this Project Agreement. This Agreement does not constitute a grant to inVentiv of any property right or interest in the Products or the trademarks owned by or licensed to Client. inVentiv recognizes the validity of and the title of Client to all its owned or licensed trademarks, trade names and trade dress in any country in connection with the Products, whether registered or not. Client represents to inVentiv that neither those trademarks, trade names and trade dress nor the promotion of the Products by inVentiv infringes on any intellectual property right of any other person or entity.

VI. HIRING PROFILE

In selecting Account Managers and RBDs, inVentiv will use the preferred hiring profiles approved by Client as set forth in Exhibit G, "Hiring Profiles." inVentiv will take reasonable steps to confirm the accuracy of information concerning background and experience received from applicants for positions of Account Managers and RBDs. inVentiv shall not knowingly employ or otherwise retain, or permit to be retained as an Account Manager or RBD, a practicing physician or a person affiliated on a professional level with or employed by any physician, physician practice or other healthcare professional or provider or a person who is in a position to unduly influence the purchase of the Products.

VII. BACKGROUND CHECKS

inVentiv shall be responsible for performing drug testing and background checks of all Account Managers after extending candidates an offer for a inVentiv Account Manager position, but prior to their hire. inVentiv represents and warrants that it will complete or cause to be completed a thorough background check of all Account Managers. This will include, Criminal Check, Social Security Check, Drug Screen, Motor Vehicle Record Check, Education Check,

Past Employer Check. inVentiv further represents and warrants that it will perform or cause to be performed background checks to confirm that no inVentiv Account Manager:

- a. is an excluded person on the Office of Inspector General's List of Excluded Individuals/Entities and is not on the General Services Administration Excluded Parties List (as of the date the background check is performed);
- b. is, so far as it is aware, an unfit or an improper individual for the performance of the Services;
- c. is, so far as it is aware, engaged in any fraudulent or unlawful activity, or other inappropriate conduct as measured by the other requirements of this Agreement.

inVentiv shall institute prompt corrective or disciplinary action against any inVentiv Account Managers who fails to meet the requirements set forth in this Exhibit A. inVentiv further agrees to cooperate and comply with all investigations by or on behalf of Client with respect to wrongdoing, or alleged or suspected wrongdoing, in respect of any obligations of inVentiv or any inVentiv Account Managers under this Agreement.

VIII. REPRESENTATIONS AND UNDERTAKINGS

(a) [*].

(b) Client represents that:

(i) it recognizes that for inVentiv to comply with its obligations hereunder, it shall need the good faith cooperation of Client to provide inVentiv with the necessary materials and assistance required to enable inVentiv to perform the Services;

(ii) the Services being provided by inVentiv are in furtherance of Client's program of marketing and promoting the Products and as such, Client is responsible for ensuring, and further, Client represents and warrants, that the Client's program being implemented by inVentiv pursuant to the terms hereof (but not the implementation thereof by inVentiv), is in accordance with Applicable Law ;

(iii) it shall ensure that none of its employees add, delete or modify claims of efficacy or safety of the Products, nor makes any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Product Literature, during the training on the Products or during any communications with inVentiv employees;

(iv) it shall ensure that none of its employees working with the Project Team or in connection with the Services, directly or indirectly instruct any inVentiv employee to pay, offer or authorize payment of anything of substantial value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order, recommend or purchase the Products contrary to any law; and

(v) neither it nor any of its employees directly or indirectly instruct any inVentiv employee to make any representations or warranties relating to the Products that conflict, or are inconsistent with applicable laws or the Food and Drug Administration approved labeling for the Products.

(vi) Client shall:

A. provide inVentiv Account Managers with all Product Literature and Product samples.

B. inform inVentiv promptly of any changes which Client believes are necessary or appropriate in the Product Literature or in information concerning the Products in order to be in compliance with all applicable federal and state law, regulations and administrative guidance.

C. respond appropriately and in a timely manner to any inquiry concerning a Product communicated to inVentiv from any licensed practitioner and communicated by inVentiv to Client.

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EXHIBIT A-1

PROJECT TEAM MEMBER REQUEST FORM

This Request for Additional Project Team members is issued pursuant to the Master Services Agreement between inVentiv Commercial Services, LLC (“inVentiv”) and Dynavax Technologies Corporation (“Client”) dated January 11, 2016 and the Project Agreement issued thereunder dated _____

PART 1	To be completed by Client Attach any relevant, helpful information
NUMBER AND TYPE OF PROJECT TEAM PERSONNEL REQUESTED	
TERRITORY LOCATION(S)	
REQUESTED HIRE DATE	
DEPLOYMENT DATE	
AUTHORIZED CLIENT REPRESENTATIVE SUBMITTING REQUEST	Signature: Name: Title: Date: Phone: Fax:
PART 2	To Be Completed by inVentiv
NEW PROJECT TEAM MEMBER DETAILS (the fees set forth below are per Project Team member added): Implementation Fee \$ _____ Added Fixed Monthly Fee: \$ _____ Target Start Date: _____	Request is Accepted, and Recruitment shall begin immediately upon Client approval of New Representative Details: (sign and date) inVentiv Contact Person: Phone:
	New Project Team member accepted and customer understands that recruiting will begin immediately: (sign and date) Client Contact Person: Phone:

EXHIBIT B
THE SALES OPERATIONS SERVICES

1.0 Executive Summary

This Exhibit B describes the scope of work, deliverables, and assumptions for field operations initial implementation and ongoing annual support for the Project (as defined in Section 3.1.1(a)). Any changes to the assumptions, deliverables, or scope of work described in this Exhibit B, or any new work request(s), will follow Section 3.1.1(d), Change Control Process of this Exhibit B.

2.0 Scope of Services

The following service areas are part of field operations initial implementation and ongoing annual support:

- Operations Management
- Customer Relationship Management (CRM)
- Customer Master Source Data & Validation
- Travel and Expense Management
- Transparency Reporting
- Data Management
- Analytics and Reporting
- Targeting, Alignment and Call Plan Administration
- Incentive Compensation Management
- Field Support Services
- Technology Training Services
- LMS System Support
- Quality Management and Assurance
- State License Verification

3.0 Scope of Work Definition

3.1.1 As part of operations management, inVentiv will provide the following:

(a)Project Management. inVentiv will provide a fully integrated project management approach for the implementation of the operations services (the “Project”). The Project will be managed by an assigned Project Manager (“PM”) who will be responsible for the following:

- (1) Leadership of Project kick-off meeting to include review of scope, timelines, and assumptions for each functional area, Project Team member introduction, and status reporting formats and meetings.
- (2) Integration of all Project activity, timelines, and deliverables across all functional areas into a consolidated Project schedule.
- (3) Leadership, facilitation, and documentation of all meetings, including meeting notes and action items.
- (4) Management of the Project schedule including task management, escalation of issues, risk identification, and interdependencies through Project documentation including:
 - (i) Issue tracker;
 - (ii) Milestone tracker; and
 - (iii) Action item tracker.
- (5) Project status meetings and Project status reporting, including weekly status reports and plan reviews with the Client.
- (6) Project close-out and lessons learned session to include any information that can be applied to the ongoing operational support of the Client after the initial implementation is complete.
- (7) Project management implementation deliverables including the following:
 - (i) Weekly implementation schedule identifying Project activities and target completion dates.
 - (ii) Weekly implementation log of risks, actions, issues, and key decisions (“RAID”).

(b)Technical Operations Management. The PM will be the lead operations point for the implementation and ongoing support of the field operations technical

services. The PM will be responsible for understanding the Client's requirements and business rules, and communication and alignment across all inVentiv operations service areas. The PM will be responsible for leading all Project status meetings, issue management, and Client and internal communications for operations services, working under the leadership of the assigned National Business Director ("NBD"). Technical operations Project implementation deliverables include the following:

- (1) Ongoing communication plan;
- (2) Technical operations deliverables document identifying standard deliverables and key business rules – delivered within six (6) weeks of the first day in the field;
- (3) Monthly technical operations status report;
- (4) Monthly operation leadership meeting and supporting documents; and
- (5) Quarterly business review meeting and supporting documents.

(c) Field Administrative Management. An Operations Manager ("OM") will be assigned to oversee and ensure that the Client and internal inVentiv teams communication across all field administrative tasks, including the following activities:

- (1) Field Administrative Management—Implementation.
 - (i) Project set up and roster management using inVentiv's proprietary master roster system;
 - (ii) Onboarding of new hires, including all aspects of administrative systems and processes (e.g., travel, CRM system, business cards, welcome memo, conference call accounts, fleet coordination, credentialing, licensure);
 - (iii) Meeting planning logistics, if requested;
 - (iv) Venue sourcing, hotel sourcing/booking, meal and events arrangements, ground transportation set up, flight arrangements, travel letter development, and budget tracking ;
 - (v) On-site meeting support available, as needed;
 - (vi) Training development and coordination;

- Identify and coordinate inVentiv/Client courses for LMS upload
- Coordinate presenters/training schedules & agendas
- LMS course completion monitoring
- Post launch mastery training plan development

(vii) Team Expense Travel and Budget Policy development.

(2) Field Administrative Management—Ongoing Support.

- (i) Roster management and distribution;
- (ii) Continuation of meeting planning logistics, as described above, either with Client vendor(s) or as a stand-alone offering;
- (iii) Monitoring Project parameters and managing eligibility and payout of incentive compensation and awards within approved Project guidelines;
- (iv) Coordinate, route, track, and report operational initiatives, questions, or directives across all of the internal administrative departments, as well as external vendors and Client home office;
- (v) Review of monthly invoicing and budgets for adherence to Project P&L;
- (vi) Coordination with sample management and fulfillment vendor (if applicable);
- (vii) Coordination with inVentiv compliance on HCP expense monitoring and reporting;
- (viii) Onboarding of backfill new hires to include all aspects of administrative systems and processes;
- (ix) Coordination of communication to the field;
- (x) Ad hoc reporting (e.g., turnover/vacancy reports, budget tracker);
- (xi) Monthly field employee roster audits; and
- (xii) Payroll processing;

- (xiii) Review and ensure all field expense reporting is completed, to include HCP reporting;
- (xiv) Field communication to include the following for the team conference call:
 - FAQ development with HR and business lead
 - Communication script
 - Project exit check list and acknowledgement
- (xv) Monitor return of inVentiv property;
- (xvi) Monitor return of Client property (i.e., samples, marketing materials, etc.);
- (xvii) Coordination with fleet department on return of vehicle (if applicable); and
- (xviii) Deactivations of all Project specific accounts (i.e., conference call/WebEx, etc.).

(d) Change Control Process. Throughout the course of providing field operations support, additional knowledge may be gained, and situations and underlying assumptions may change. A component of the Project management process is to identify the changes and make informed decisions, especially with regard to functionality, schedule and cost. The change control process enables inVentiv and its clients to maintain a shared vision for the Project. The objectives of change control are to:

- (1) Assess the impact of scope changes on Project schedules, resources and pricing;
- (2) Provide a formal vehicle for approval to proceed with any changes to the Statement of Work;
- (3) Provide a Project audit record of all material changes to the original Statement of Work; and
- (4) If requirements arise that are outside the scope of this Exhibit B, a Change of Scope document (or an amendment to the Statement of Work, as applicable) will be submitted for Client approval following the below process:
 - (i) Client requests additional requirements for new functionality or deliverables outside the scope of work identified.

- (ii) inVentiv reviews change, meets with Client and internal team members to understand and scope Client expectations regarding business need, timelines, and other deliverable expectations.
- (iii) inVentiv provides Change of Scope (or Amendment or new SOW) document, which outlines work effort, timeline and pricing impacts of the change. Pricing will be determined based on standard rates provided below.
- (iv) Client accepts proposal and signs Change of Scope (or Amendment or new SOW) document which authorizes work to begin on the change request.

(5) Standard Pricing Table.

Role	price/HR
Software Development	[*]
CRM Configuration	[*]
Data Management	[*]
Alignment/Call Planning	[*]
Incentive Comp Modeling/Design	[*]
Analytics & Reporting	[*]
Project Management	[*]
Testing	[*]
IC Administration	[*]
Training (Content/Delivery)	[*]
Hardware/Help Desk	[*]

3.2 Customer Relationship Management (“CRM”)

3.2.1 CRM; Client Configuration and Available Functionality. inVentiv will provide a CRM application. Additionally, within its CRM application, inVentiv will set-up a single, Client-specific, dedicated CRM environment configured specifically to the Client’s business rules (the “Client Configuration”). The core functionalities within the Client Configuration are as follows, and will be configured by inVentiv upon selection by Client:

- (a) Customer profile management across account types (individuals and organizations);
- (b) Call recording, reporting, and loading of Call plans;
- (c) Closed-Loop Marketing (“CLM”), loading and presentation of digital media as part of integrated call record;
- (d) Sample management and recording of samples and physician signature capture as part of integrated call record, including Prescription Drug Marketing Act (PRBDA), CFR Part 11 Validation, if requested by Client;
- (e) Medical Inquiry Request Form (“MIRF”) including physician signature capture;
- (f) Field Coaching Report (FCR) configuration;
- (g) Pre-established reports and dashboards to enable field and field management performance (online only); and
- (h) iPad/online platform options including online/home office PC, field tablet PC, and iPad to support mobility needs and improved customer interaction.

3.2.2 **CRM; Client Configuration Development and Implementation.** CRM implementation will be led using an agile development approach including the following deliverables:

Project Deliverable	Definition
Initial Requirements	Demonstration of the Client Configuration; and discussion of Client needs and business environment to support the general usage and end-user experience; will include accounts, functions, Call types, products, customer profile maintenance, etc.
Alpha Review	First iteration of the Client configuration based on requirements gathered in the Initial Requirements session. Detailed demonstration of the Client Configuration for more in-depth review of Client requirements.
Configuration Requirements Document (“CRD”)	After the Alpha Review, inVentiv will provide the Client with a draft CRD document which summarizes all end-user system requirements taken from both the Initial Requirements and Alpha Review sessions. The CRD will form a basis for the final Client Configuration specifications, risk assessment, testing, training, and validation (if applicable).

Project Deliverable	Definition
Beta Review	The final phase of the Client requirements will be a Beta Review, which will allow for any changes to the Client Configuration system requirements for final testing and production readiness.
CRD Sign-Off	Any changes or additions to the Client Configuration requirements during the Beta Review will be incorporated into the final CRD and submitted to the Client after the Beta Review session for final approval and signature.

3.2.3 Client Configuration Assumptions. The scope of the Client Configuration CRM delivery and associated timelines for the Project assumes the following:

- (a) Necessary Client members are available for the Initial Requirements, Alpha Review, and Beta Review meetings (each typically 3 hours), based on the weeks assumed in the agreed upon Project plan (Alpha Review/Beta Review may be done via WebEx);
- (b) Sign-off of documentation within 5 days of delivery by necessary Client members;
- (c) No customization of code outside of CRM provided configuration capabilities;
- (d) Use of standard MIRF functionality and data extracts to medical information;
- (e) Client Configuration/CRM does not include Adverse Events/Pharmacovigilance (“AE”) reporting or recording. An alert is setup in the CRM system to remind field users of the appropriate number/process to communicate to HCPs;
- (f) Linking to company or external web-based systems within CRM tab structure;
- (g) Access to inVentiv Veeva Vault for Client approved content including: CLM presentations and approved email templates. Alternatively, inVentiv Veeva Vault may be setup to attach directly to Client internal Veeva Vault system in cases where Client is using Veeva Vault for internal Medical, Legal, Review (“MLR”). inVentiv Veeva Vault is not used for internal Client MLR usage, only for field delivery of approved content;
- (h) Sample management functionality, if required, and data feeds for sample shipments, SLN validation, and sample product information as determined by Client requirements;

- (i) Inclusion of sales data within standard Veeva reporting functionality (online only);
- (j) Field Coaching Report originates from manager, not representative, including data entry only. Form will not be pre-populated with any data from any source;
- (k) Call history within the Sales Force Automation (“SFA”) system not to exceed 15 months (5 Quarters) without purchasing additional data storage from Salesforce.com;
- (l) External access for Client home office administrators can be granted with change control processes in place to ensure integrity of inVentiv production environment, with additional license costs as dictated by home office license pricing in contract;
- (m) Ongoing support for CRM system including tier 2/technical support for escalated calls from field support desk, and home office support needs; and
- (n) Ongoing support assumes up to [*] hours of CRM work effort annually, inclusive of production support, system upgrades, technical support, and/or enhancements. Any unused portion of the annual hour allotment may not be carried forward into subsequent years. Additional work-effort beyond the [*] hour annual allotment will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

3.3 Customer Master Source Data and Validation

3.3.1 Veeva Network and Veeva OpenData Validation.

- (a) inVentiv shall provide a near real-time customer validation process leveraging the integration of Veeva Network and Veeva OpenData. This combination gives direct access to Veeva OpenData for adding and changing of HCP and HCO data, which allows for field users to search, add, and immediately pull-down HCPs/HCOs industry standard identifiers and compliance information, such as SLN and IDEA, upon adding the new prescriber, as opposed to waiting the standard 2-3 weeks for weekly data exports and validation.
- (b) Client and inVentiv’s targeting and alignment team will also have access to Veeva OpenData for sales or marketing research, such as to identify initial target universe, ongoing target adjustments, new product or market evaluations, etc.

(c) The Veeva Network service includes the following:

- (1) Configuration and support for utilizing Veeva OpenData and the Veeva Network to allow for this Customer Master Data solution to control the universe in the CRM system and to provide for data stewardship services via Veeva OpenData provided controls.
- (2) Data change requests can be submitted by field users to the Veeva OpenData data stewards, which increases efficiency and decreases timelines associated with routine action request processing for universe changes discovered by the field.
- (3) The Veeva Network account search will allow for the field to search the Veeva OpenData Customer Master Data for any HCP or HCO that meets the search criteria, and provides the ability to add that HCP or HCO to their Veeva CRM territory. The information included is pre-validated by Veeva OpenData so an eligible HCP can be sampled immediately. Additionally all valid address information known for that account will be brought down with the HCP or HCO selected.

(d) The Veeva OpenData service includes access to the following data set:

- (1) Licensed field and home office users have access to entire customer universe (HCPs, HCOs, addresses, affiliations) in the Veeva OpenData customer universe.
- (2) Usage of compliance data scrub — for industry standard identifiers SLN, NPI, DEA #s for initial and ongoing data validation.
- (3) Usage of data hygiene scrub — for HCP demographic data such as address, specialty etc. for initial data validation.
- (4) Access to email address data is not included in standard offering but may be available on a per record basis for marketing initiatives as needed and is recommended for usage if Client is implementing enhanced approved email functionality (not included in base CRM license).

3.3.2

Validation Fee Structure.

inVentiv services will include a user license for the Veeva Network application and Veeva OpenData services based on a per user, per month

fee assuming the same user count as the number of licenses purchased for the Client Configuration.

3.4 Travel and Expense Management

3.4.1 Travel & Expense Set-Up and Ongoing Services. inVentiv shall leverage its then current travel and expense (“T&E”) management system application (and solution provider) (collectively, the “T&E Management Solution”), currently Concur, for capture and reimbursement of all expenses incurred by inVentiv employees recruited for the Client’s Project, and for HCP data capture necessary for transparency reporting. The T&E Management Solution assumes the following:

- (a) Required Client members are identified and available for requirements gathering;
- (b) Client’s requirements align with the standard baseline Concur configuration, (i.e. able to utilize existing expense types, approval workflow, etc., without customization);
- (c) Completion of Configuration Request document for Project set-up based on Client spend limits and business rules;
- (d) Acceptance of inVentiv universe for HCP selection utilizing Medpro Concur Connect;
- (e) Ongoing support for Concur T&E management system including tier 2/technical support for escalated calls from field support desk;
- (f) Changes to or additional audit rules may be requested post-deployment;
- (g) On-going roster management as teams expand or re-align (including territory and manager changes);
- (h) Information on areas such as Amex cards, mileage rates, report approvers, etc. are communicated and decided on at onset of implementation based on Client business rules;
- (i) T&E management system setup and support is only provided for inVentiv employees. If any Client employees are supported, Client will be responsible for the deployment of the T&E management system and capture of any HCP meal spend, etc. for the Client employees;
- (j) Coordination of Learning Management System (“LMS”) Project set-up and communication of system access and viewing of Concur module to new hires/end users;

(k) Inclusion of Expense Management in Technology Training sessions; and

(1) Tracking of completed Concur module review in LMS per user.

3.4.2 Travel & Expense Deliverables. The T&E management system application work stream will be managed by the Operations Manager, the Concur system subject matter expert, and the compliance lead, and will include the following deliverables:

Project Deliverable	Definition
T&E Guidelines	General inVentiv guidelines provided to assist the Client in developing their T&E program; this can be reviewed and modified by Client as required.
Compliance Business Rules Document	Detailed document describing all compliance business rules associated with the Client Project. A draft will be provided with inVentiv's base business rules and guidance with review and modifications as needed, and approval by inVentiv and Client.
ERD (Expense Requirements Document)	Detailed document describing standard Concur functionality and Client-specific business rules based on requirements gathering and configuration request. Following internal review, final document will be reviewed and approved by inVentiv and Client.
Training Documentation	Training documentation provided to field users and management with guidance on T&E management system application and compliance business rules and usage.

3.5 Transparency Reporting

3.5.1 Background. H.R. 3590, Section 6002: "Transparency Reports and Reporting of Physician Ownership or Investment Interests," also referred to as the "National Physician Payment Transparency Program" a/k/a the "OPEN PAYMENTS" or "Sunshine Act" and H.R. 3590, Section 6004: "Prescription Drug Sample Transparency," requires certain data collection and reporting regarding payments or transfers of value and drug sample distribution to physicians. All transfers of value by inVentiv to an HCP or HCO must comply with Applicable Law, Client's Code of Business Conduct and Ethics (a copy of which shall be provided by Client to inVentiv) and Client's applicable policies provided by Client to inVentiv.

3.5.2 Data Management. inVentiv will provide the following data management services to Client:

- (a) For Clients utilizing inVentiv Concur for HCP-related meal expenses, regular reports of HCP-related meal expenses in inVentiv's standard format;
- (b) For Clients utilizing inVentiv CRM, regular reports inVentiv's standard format of items of value that are non-sample items left with HCPs;
- (c) For Clients utilizing both inVentiv's Veeva CRM and J. Knipper and Company for sample accountability, inVentiv will provide a report of drug samples left with HCPs;
- (d) For all provided reports, inVentiv will run full-cycle system testing and support UAT testing; and
- (e) All reports will be clearly defined in terms of layout, content and delivery in the Data Requirements Document.

inVentiv will work with Client in the data requirements process to confirm the file format, data elements, file delivery process and frequency to meet Client specifications for transparency reporting and Client System Integration. inVentiv's Monitoring and Auditing processes for transparency reporting is detailed in Exhibit C, Compliance.

3.6 Data Management

3.6.1 Generally.

- (a) inVentiv will provide data loads and data integration services for standard data imports and exports. Data management services includes data flowing to and from the Veeva CRM application, including Client data sources, third parties (i.e. sales data), or service partners. The data management team will work with the Veeva CRM, and analytics and reporting tools, to ensure that all Client business rules and data requirements are understood and planned for in the overall implementation plan.
- (b) A full description of all data files and formats for data interfaces will be provided in the Data Requirements Document ("DRD"), which will be included as part of the Project Plan with necessary approvals from the Client and Project leads. The DRD will also include a Production Schedule, for ongoing data management services.

3.6.2 Data Loads, Imports and Extracts—Standard. The Project assumes use of standard data loads and file formats for all initial and ongoing data support as provided below:

(a) Standard initial data loads shall use agreed upon inVentiv/Client formats including:

- (1) Territory hierarchy;
- (2) Customer universe, alignments, and Targets/Call plans;
- (3) Product information; and
- (4) Call history (if required).

(b) Standard reoccurring data imports shall be conducted at set frequencies and in agreed upon formats as needed for the following:

- (1) Prescriber/account sales data (weekly & monthly);
- (2) Prescriber payer data (weekly & monthly);
- (3) Call Plan/Targets (quarterly); and
- (4) Customer universe updates—validation responses (weekly).

(c) Standard reoccurring data extracts shall be provided at set frequencies to either home office or third party vendors as needed for processing to include:

- (1) Call/activity data (weekly or monthly);
- (2) Medical inquiries (daily);
- (3) Sample activity (weekly or monthly);
- (4) Extracts supporting Transparency Reporting in Section 3.5 (monthly or quarterly);
 - (i) RBDE Spend data from Concur;
 - (ii) Items of value, open payments reports;
 - (iii) Hand-carry sample reports for ACA 6004 (Knipper clients only); and
- (5) Customer Universe Validation Requests (weekly).

(d) Standard data maintenance services will be provided for the ongoing support of the systems and data at fixed frequencies as defined below to include:

- (1) State license validation process to reduce field impact in sampling (weekly);
- (2) PDRP flagging on accounts (monthly);
- (3) Routine merging of accounts (quarterly);
- (4) Setup of integration between Veeva CRM and data warehouse, which allows roster, Territory hierarchy and Product management to be seamless (daily);
- (5) Processing of action requests (Client data changes) (quarterly);
- (6) Time off Territory and holiday updates (monthly);
- (7) Ongoing maintenance of sales and payer data (weekly or monthly based on sales data provider availability);
- (8) Training database setup and management (quarterly);
- (9) Tier 2/technical support for data issues routed from the Field Support Desk (daily);
- (10) Customer sales data extracts for IC (as defined in Section 3.10) processing (monthly); and
- (11) Customer sales data and Call/activity extracts for A&R processing (monthly).

(e) Ongoing support assumes up to [*] of work effort monthly for the ongoing data management services as provided in the DRD. Any unused portion of the monthly hour allotment may not be carried forward into subsequent months. Additional work-effort beyond the [*] monthly allotment will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

3.6.3 Assumptions. The scope of the data management delivery and associated timelines for the Project assumes the following:

Project Deliverable	Definition
Initial Requirements	Discussion of client needs regarding data loads, extracts, and imports and finalization of Project plan and scope based on SOW assumptions and change management process

Third Party Agreements (TPA)	inVentiv will secure, in coordination with Client, any rights and licenses that inVentiv needs from external vendors such as sales data companies which require TPA for data services to be provided
DRD (Data Requirements Document)	inVentiv will provide the Client with a DRD document which summarizes all data loads, imports, and extracts, as well as any business rules, frequencies, and formats associated with the data services to be provided as part of implementation and ongoing data management services, the DRD draft will be reviewed, modified as needed, and signed by the Client to confirm Project deliverables
Test Files	The Client or third parties will provide needed test files in specified formats and agreed dates in the Project plan based on the implementation schedule
Final Production Files	The Client or third parties will provide final production files in specified formats and agreed dates in the Project plan based on the implementation schedule

3.6.4 Non-Standard; Changes. Any additional data feeds not included in the standards as defined above, or changes to data exchanges or maintenance subsequent to the approved DRD will follow the change control process and rate schedule set forth in Sections 3.1 and 3.1.1(d) respectively.

3.7 **Analytics and Reporting**

3.7.1 Veeva CRM Dashboard Reporting.

(a) Reporting Generally; User Types. The Project assumes general field activity reporting will be provided in the Veeva CRM Dashboard Reporting environment utilizing inVentiv's pre-configured reporting tools to optimize field performance and implementation setup time. inVentiv reporting will be provided for the following user types aggregated based on the user type's span of control:

- (1) Representative (Territory level);
- (2) Field Management (regional level); and
- (3) Home Office (national level).

3.7.2 Veeva Report Configuration and Templates.

(a) inVentiv will configure the reporting tools to include Client specific fields and terminology, where applicable, within Veeva and Salesforce.com guidelines. Veeva requirements, development, and deployment will follow the requirements and format as provided in the Veeva CRD as stated in Section 3.2, and may include the following: field activity, including the following: Call activity, Call plan adherence,

sample activity, CLM utilization, synchronization monitoring, manager exceptions, and/or administration.

(b) Report Templates. The Veeva template field reporting package is designed to drive sales behavior in the following ways:

- (1) Evaluation of prescriber sales for pre-Call planning from account summary report;
- (2) Measure that the most valuable drivers of sales were detailed and sampled in accordance with the recommended Call plan - account/physician –
 - (i) Average Calls per day –reviews Call activity against Target or segmentation;
 - (ii) Reach and frequency can be found on analytics tab;
 - (iii) Call plan information can be found on the Call plan tab; and
 - (iv) Call Plan Analysis Report can be found on the analytics tab.
- (3) Measure the impact of detailing and sampling on sales –
 - (i) Effort vs. results report can be found on the analytics tab.
- (4) Examine the landscape for the product to identify top sales accounts and potential –
 - (i) Territory sales analysis—reviews trends in Client Product and competitive landscape; can be found on analytics tab;
 - (ii) Territory payer analysis –examines payer information; can be found on analytics tab; and
 - (iii) Territory comparison report—compares sales performance at the Territory level for all territories within span of control; can be found on analytics tab.
- (5) Report Template Table.

Template Reports	Base Assumptions	Standard Frequency
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Template Reports	Base Assumptions	Standard Frequency
Account Summary	Prescriber based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client
Activity/ Administrative	<ol style="list-style-type: none"> 1.Reviews key territory and/or district performance indicators with drill down details for: <ol style="list-style-type: none"> a. Interactions b. Detailing c. Sampling 2.Review key territory and/or district administrative metrics with drill down details 3.Any information collected within a check box or drop down list into the Veeva systems can be aggregated into a dashboard element. 4.Text box information can be rolled into a report but not the dashboard. 5.Dashboards can have up to 20 measurement elements 6.All Dashboard elements are pictorials which aggregate data from an underlying report 7.All pictorials are flexible but limited to two dimensions 8.Color selection is not an option 9.Filters can be applied to comparable data 10.Reports can be filtered by user level (Field, Management, Home Office) 11.Other Reportable Activity: <ol style="list-style-type: none"> a.System Utilization b.Pending Interaction (Exception/incomplete information) c.Time off Territory d.Synchronization Reports e.Interaction by Date and Time f.Field Action Requests 12.Account Demographics <ol style="list-style-type: none"> a.Target/Non-Target b.Account Type (practitioner, pharmacy, staff, etc.) c.Specialty d.Segmentation e.Custom Profile Attributes 13.Closed Loop Marketing (CLM) <ol style="list-style-type: none"> a.Slide Utilization as % of Calls b.View Duration c.Ranking of Slides by View count and Average Duration 	Real time as of last synchronization and refresh

Template Reports	Base Assumptions	Standard Frequency
	d.Viewer Reaction (Positive, Neutral, Negative)	
Reach and Frequency	Adapted to specific activity measurements and goals within set up matrix (calls, targets only, reach, frequency, sample distribution)	Real Time as of last synchronization and refresh
Average Calls Per Day	Average Calls Per Day versus goal	Real Time as of last synchronization and refresh
Territory Sales Analysis	1.Adapted to specific product/market definition 2.Monthly prescriber based product level prescription data; Up to 3 promoted products	At same frequency as sales data (aka prescription data) delivery to Client
Territory Comparison (Mgmt. supplement)	1.Adapted to specific product/market definition 2.Monthly prescriber based product level prescription data; Up to 3 promoted products 3.Comparison of sales data amongst the assigned span of control	At same frequency as sales data (aka prescription data) delivery to Client
Territory Payer Analysis	1.Monthly payer based product level prescription data 2.Analysis of the prescriber payer 3.Top payers 4.Comparison of payer market products	At same frequency as sales data (aka prescription data) delivery to Client
Effort vs. Results aka Impact Report	1.Adapted to specific product/market definition 2.Up to 3 promoted products 3.Monthly prescriber based product level prescription data	At same frequency as sales data (aka prescription data) delivery to Client

3.7.3 Custom Analysis & Insights.

Analysis or custom one-time/ongoing reports will be provided at an assumed amount of up to [*]. Any unused portion of the monthly hour allotment may not be carried forward into subsequent months. Additional work-effort beyond the [*] monthly allotment will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

3.8 Targeting, Alignment and Call Plan Administration

3.8.1 Generally, inVentiv will provide targeting and sales force alignment services for optimization of key targets. The goal of these services is to:

- (a) Optimize geographic coverage on the most valuable Targets while balancing Territory workload;

(b) Target list generation based on business-specific workload parameters including the incorporation of any segmentation, detailing and frequency provided; and

(c) Identification of uncovered white space geography.

3.8.2

Deliverables.

(a) Metropolitan Statistical Area (MSA) overview;

(b) Alignment summary including coverage of top targets;

(c) Uncovered geography summary;

(d) Mapping at territory, district and national levels;

(e) Zip-Terr;

(f) Span of control; and

(g) Target list.

3.8.3

Assumptions.

(a) The scope assumes the following:

(1) Client will provide the initial alignment during the Project implementation.

(2) Alignment will be created utilizing inVentiv's preferred alignment software;

(3) Territory workload parameters and Project assumptions are agreed upon before work starts;

(4) All third-party agreements are signed off on before work starts;

(5) If third-party data purchased by inVentiv will be passed through to Client;

(6) Client will supply physician level universe which will include best address and any workload specific data points (i.e., Rx, Deciles, etc.);

(7) One (1) per-deployment interactive alignment session for the field managers for minor geographic tweaks; and

(8) Quarterly Target or Call plan updates will be managed through the Veeva Action Request process, with timing provided for minor home office changes. This will be done for alignment and Target updates each quarter, with District Manager/Sales Management reviews, per the agreed upon process between Client and inVentiv. Ongoing support assumes up to [*] of work effort quarterly, inclusive of Target and Call plan updates. Any unused portion of the quarterly hour allotment may not be carried forward into subsequent quarters. Additional work-effort beyond the [*] quarterly allotment will require work estimates and Change of Scope as detailed in Section 3.1.1(d), to be coordinated by the PM.

(9) One (1) re-alignment within the first [*] months of execution, as requested by Client.

(b) Items not included in the assumptions:

(1) Major realignments or re-targeting exceeding >[*] changes in territories, geography, or segmentation such as new Target strategy, expansions, or down-sizing; and

(2) Additional mapping and data analysis.

3.9 Incentive Compensation Management

3.9.1 Generally, inVentiv incentive compensation management will design and /or implement an annual incentive compensation (“IC”) plan and administer quarterly payouts. inVentiv IC personnel will facilitate an IC assessment meeting to ascertain scope of work, IC plan parameters, data availability, budget, IC plan goals and bonus culture. Sessions will be led by inVentiv IC employees experienced in the discipline of IC plan design and field performance measurements. The assessment sessions are strategically structured to aid in the IC plan design, consisting of metrics aligned to business strategy. After the IC plan design has been approved by the parties, the inVentiv incentive compensation department will implement, manage and administer IC plan.

3.9.2 Standard IC Services are inclusive of the following:

(a) Two IC plans in the first year; one for the first six (6) month period, and one for the subsequent six (6) month period. Thereafter, inVentiv will provide a single annual IC plan for each Client team (i.e. Sales and Sales Managers) for the covered field employees, with no more than two (2) Plan Updates (as defined herein) per year. Each IC plan shall be reviewed and approved by Client before it is finalized and implemented. A “Plan Update” is defined as a change, which does not alter the IC plan structure (i.e. change to a payout grid or goal) thus resulting in an amendment to the IC plan. Changes to IC plan structure, which require a new set of modeling, design work, and/or plan communication documentation are considered a “New Plan,” and may be subject to a separate Statement of Work (“SOW”). Any change to an approved IC plan that pertains to incentive compensation based on sale of product or other revenue or unit based measure, must be reviewed and approved by Client.

(b) The components of an IC plan will include the following:

- (1) Plan concept presentation deck;
- (2) Formal plan document with electronic signature;
 - (i) Inclusive of:
 - Plan design measurements
 - Business rules
 - Data crediting
 - Calculations
 - Participation rules
 - Terms and Conditions

(ii) IC Plan document will be reviewed by the following:

- Sales Leadership
- inVentiv Human Resources
- inVentiv Corporate Compensation
- inVentiv Authorized Legal Client

(3) Monthly spreadsheet (“IC Grid”) of calculated results (dependent on data availability and IC plan design);

(4) Monthly field scorecards (dependent on data availability and IC plan design);

(5) Quarterly payout administration in accordance with the inVentiv payroll calendar;

(6) A single contest/special performance for field force per year to include:

(i) Contest Concept Presentation Deck;

(ii) Formal Plan Document with electronic signature;

(iii) Single payout administration in accordance with the inVentiv payroll calendar; and

(iv) Single contest grid and/or scorecard of contest results.

(7) A single annual President’s Club contest/trip to include:

(i) Results published in conjunction with the monthly IC reporting process.

(8) Additional services and changes will be subject to the Change Control Process and subject to an amendment.

3.9.3 IC Plan Deliverables and Timelines.

(a) Design Phase.

Category	Description	Duration/Timeline
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IC Plan Meeting(s)	Initial Meeting to discuss: <ul style="list-style-type: none"> •Corporate Philosophy •Sales Goals/Objectives •Sales/Marketing Strategy •Business Rules •Data Inputs •Eligibility Requirements 	1 day — initial meeting; subsequent follow-up meetings may be held to discuss pending topics or matters requiring further discussion from initial meeting.
		Maximum timeline 3 weeks
IC Modeling	Based on inputs derived from initial IC meeting(s), inVentiv will create/provide IC deck illustrating: <ul style="list-style-type: none"> •Recommended IC plan(s) •Payout Scenarios/Distribution 	<ul style="list-style-type: none"> •1 week to provide recommendation •1 week for feedback/follow-up •Additional time may be needed if data is required for modeling
Field Communication	IC Plan communication includes: <ul style="list-style-type: none"> •PowerPoint deck (Management Team & Sales force) •Word/PDF document (for IC plan participants/acknowledgement) 	3 weeks (maximum) once IC plan has been finalized.

(b) Implementation Phase.

Category	Description	Duration/Timeline
IC Plan Programming	<ul style="list-style-type: none">•Data Process Setup•SQL Programming•User Interface Setup•Report/Scorecard Programming•KPI/MBO Programming (if applicable)•Acknowledgement Portal Setup•Administration Portal Setup•Programming QC & Testing•Validation & QC of IC plan programming (independent of Programming QC)•Minor changes (cosmetic, etc.)	Maximum of 3 weeks after receipt of initial sales data file in final format

(c) Maintenance/Management Phase.

Category	Description	Duration/Timeline
Plan Administration	<ul style="list-style-type: none">IC plan processing<ul style="list-style-type: none">•Report Generation<ul style="list-style-type: none">oPayout Grid/SummaryoScorecardoManagement Summary•IC plan QC•Report Distribution•Roster Management•Eligibility; LOA; PIP; New Hire•IC Portal Maintenance•Acknowledgment•Administration	4 weeks after receipt of monthly sales data file

As IC is a pass through expense to Client, inVentiv encourages Client input on IC plan design. In instances where Client has given input into the IC plan design

or when inVentiv implements an IC plan design created by Client, Client acknowledges and agrees that it shall use best efforts to timely approve such IC plan design, The foregoing notwithstanding, in the event field force goals, dependent data, Client requested input, and/or plan documentation are not approved by Client and/or acknowledged by the field force within forty-five (45) calendar days into the then current IC plan period, inVentiv reserves the right to implement either the IC plan which was utilized in the prior IC period or an inVentiv standard best practice IC plan, and Client acknowledges that by engaging inVentiv to perform incentive compensation management, Client is expressly consenting to the foregoing.

3.10 Field Support Services

3.10.1 Help Desk. The inVentiv field support service desk supports inVentiv systems and operational processes for field user readiness and performance.

- (a) Field support service desk hours are Monday through Friday, 8am-10pm, Eastern Standard Time
- (b) Standard inVentiv metrics and KPIs for call and ticket resolution
- (c) Field Support can be reached via telephone or via email
- (d) Knowledge base will be supplied for field support service desk based on Client business rules and system configuration
- (e) Standard monthly reporting will be provided along with post-rollout daily monitoring reporting for 2 weeks following each field deployment

3.10.2 Asset Management.

- (a) inVentiv will provide asset management services ranging from hardware procurement, to configuration and deployment, and includes tracking IT assets throughout the life of the Project. inVentiv maintains a suite of standard Windows images and custom images available as needed. Client hardware is asset tagged, scanned and secured in a locked area with restricted access for designated IT personnel.
- (b) Standard hardware platform includes:
 - (1) Field laptop with carrying case
 - (2) Apple iPad with cover
 - (3) Printer

- (c)Users are given inVentiv-hosted email boxes with the option to configure with Client-like domains/addresses to give the look and feel of a Client employee.
- (d)All Client launches include a [*] spare pool of hardware to be used as replacements in the event of breakage or theft/loss. Repairs/replacements are shipped out to the end-users within 48 hours of receipt of broken hardware.
- (e)Passcode-protected iPads are deployed using our mobile device management software with remote-wipe capabilities for added security. App packaging and deployment capabilities are available. For clients opting for iPads with data plans, we can activate with one of the major carriers prior to shipment and then maintain that data plan throughout the life of the contract.

3.11 Technology Training Services

3.11.1Generally. inVentiv will provide technology training services for the Project Team. The technology training services format follows inVentiv’s core training content and facilitation approach. Training delivery assumes the following structure:

- (a) Pre-learning home study training (e-modules)
- (b) Face-to-face training (up to 1 day)
- (c) Post-training mastery (up to 2 hours WebEx)

3.11.2Content. The training content will include key inVentiv supported field hardware and applications including the following topics: iPad basics, Concur T&E, HCP Spend Capture, Veeva CRM, Veeva Analytics & Dashboards, and Customer Maintenance. New hire training will be delivered using the same content developed for implementation and offered at the frequency of **one class per quarter**, with the preferred Client format of either WebEx or face-to-face delivery. Additional training is offered as needed following the Change of Scope process in Section 3.1.1(d) of this Exhibit B.

3.12 Learning Management System (LMS)

inVentiv will supply Client with our standard LMS system for the delivery and tracking of all online training. Standard LMS reporting will be provided to internal inVentiv leadership and Client for communication of training completion and verification of required compliance training. The LMS can contain a combination of inVentiv and Client-created content to enable its use across all

product, selling skills, soft skills, and compliance training and service as a central repository for all training records.

Standard LMS Service Levels are indicated in the below table:

Standard SLA Agreement Content Load	
Task/Request	Timeline
Simple PDF Load	1-2 days
Simple SCORM Load	2-4 days
Simple Assessment	2-3 days
Registrations/Assignments for existing activities and users	24 hours
Add Additional user (upon notice)	End of next business day
	24 hours
Complex Assessment	3-5 days
Complex Course with Assessment	5-7 days
High Stakes/Large Assessment	5-7 days

3.13 Quality Management and Assurance

3.13.1 Quality Management System (QMS). All Client implementations are managed via an approved set of Standard Operating Procedures (SOPs) which are part of inVentiv's Quality Management System (QMS) under the Head of Quality Assurance. Key processes such as project governance, document control, CRM implementation and training are required for assigned operations personnel. Other SOPs such as Change Control, security and access control, asset provisioning, and CRM end-user training are additional required training for implementation teams, which are also delivered and tracked within inVentiv's Learning Management System (LMS).

3.13.2 System Validation (Sampling Only). When required by sampling, formal Computer System Validation (CSV) is conducted by professional validation resources following inVentiv's System Validation SOP. The work is driven by the approved Configuration Requirements Document (CRD), and includes a Validation Plan, Operational Qualification, Performance Qualification, Test Evidence (typically screen shots), Deviation Reports, Traceability Matrix and a Validation Summary Report.

3.13 State License Validation

Client shall pay inVentiv a per-lookup fee in accordance with the following, as requested:

Look-Up Type	Fee Per Lookup
Auto Match	[*]
Manual Match	[*]
Data Hygiene Record	[*]
HCP Email ID	[*]

4.0 Operations Services Termination and Data/System Conversion

inVentiv will retain all documented business requirements, system configurations, and data collected during the term of the Client agreement (“Agreement”). If the Client wishes to convert the field team pursuant to the Agreement (if permissible thereunder), Client may have the option to continue on with inVentiv-provided operations services to limit the disruption of field operations and leverage custom built systems, business rules and data integration. In such a case, a separate agreement will be established to confirm the scope and fees for any stand-alone operations services required. Alternatively, the parties may agree to convert the pre-built CRM configuration utilized for Client, for a fee mutually agreed to by the parties, to cover the migration of data, requirements documentation, and transfer of CRM configuration ownership, training on Client configuration settings and administration, as well as the Project management of the operations conversion, all to ensure a successful migration. Additionally, if the Client does not want to migrate the inVentiv CRM configuration, the option may be made for inVentiv to transfer Client data, business rules documentation, current data production schedules, and custom reporting formats for a fee mutually agreed to by the parties. If inVentiv provides any migration or materials, Client is solely responsible for the system knowledge and performance post-conversion. inVentiv may provide additional services based on the standard rates provided in the Change Control 3.1.1(d) of this Exhibit B.

EXHIBIT C
COMPLIANCE SERVICES

1.0 Executive Summary

This Exhibit C describes the work required for the initial implementation and ongoing services of the Selling Solutions Commercial Compliance Services. Any changes to the assumptions, deliverables, or scope of work described in this document or any new work requests will follow the procedure set forth in Section 3.1(d) (Change Control Process) of Exhibit B.

2.0 Scope of Services

This Exhibit C defines the work related to the following service areas for the initial implementation and the ongoing services of the Selling Solutions Commercial Compliance teams within the following areas:

- Compliance Services
- Monitoring & Auditing

3.0 Compliance Services

inVentiv will provide compliance services aligned with the philosophy and physical requirements of OIG's Compliance Program Guidance and that are consistent with Applicable Law, Client's Code of Business Conduct and Ethics (which shall be provided to inVentiv by Client), and relevant Client policies provided to inVentiv by Client in correlation with the following activities.

3.1 Pre-Launch Activities

- (a) Initial interaction and fact finding with clients.
- (b) Development and consultation in regards to the implementation of client specific business rules.
- (c) Creation of all training materials, (home study on Learning Management System) and live training modules. inVentiv will discuss its training materials with Client to include Client's agreed upon business rules.
- (d) Work with, post and train relevant personnel on specific policies required by the Client, help develop SOP's if required.

3.2 Launch Activities

- (a) Loading and testing of all on-line training to be conducted during home study, as well as assessments to test knowledge and competency. All tracking and reporting of results from the training.

(b) Live training to be conducted at launch meetings, POA' s at client site's or in-house.

3.3 Ongoing Activities

- (a) Training for all new hires/backfill for replacement personnel or expansions at client site's or in-house.
- (b) Continual monitoring and updating, in consultation with Client, if guidelines, laws, state requirements, or client business rules change during the course of the year.
- (c) Corporate Integrity Agreement (CIA) obligations, additional training requirements, debarment of personnel, and annual certification of personnel and reporting to the client.
- (d) Updates and assistance in supplying the necessary oversight and training at POA meetings during the year.
- (e) Compliance/Representative ride-along program to monitor the field personnel in regards to their compliance requirements as agreed to by the client, at a possible fee paid by Client .

3.4 Enforcement and Monitoring

- (a) inVentiv adheres to an "Open Door Policy" and encourages employees to discuss issues and or concerns of misconduct with their manager or other senior personnel, Human Resources, or a member of the Compliance team.
- (b) inVentiv also encourages and supports an 24 hour anonymous hotline 7 days a week if the person making the report requires or wishes to remain anonymous.
- (c) inVentiv has an Investigation Policy in place so as to insure continuity in enforcement, and transparency with our personnel and clients so proper adjudication is achieved.
- (d) inVentiv will timely share the results of all investigations, audits and monitoring it conducts pertaining to Compliance with Law and/or applicable Client policies.

4.0 Monitoring & Auditing

inVentiv uses the industry standard T&E system, Concur, to capture all expense reimbursements and HCP meal spend. The Compliance Monitoring & Auditing team will assume the following:

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- (a) Standard Concur HCP expense fields and set-up are used for projects;
- (b) Post Manager Compliance Audit of expense reports that contain HCP meal spend for appropriateness and adherence to Client policy on Interactions with Healthcare Professionals;
- (c) Ensure accountability for problem identification, oversight, follow-up, and resolution generated by the audit findings, including investigations initiated for cause, those based on anonymous reports of potential misconduct or otherwise as directed by legal counsel; and
- (d) RBDE (Direct Marketing Expense) data extract for Client tracking and reporting for Federal and State HCP transparency requirements (per client requirements as documented in the data requirements document).

**EXHIBIT D
TRAINING SERVICES**

1.0 Executive Summary

This Exhibit D describes the work required for the initial implementation and ongoing operation of the Training Services to support the Project Team by inVentiv Health Learning Solutions

2.0 Scope of Services

inVentiv will provide training services for the inVentiv Field Team employees; to include, in addition to any Client-provided content, the following inVentiv content:

- inVentiv Compliance Training
- inVentiv Administrative Training
- inVentiv Technology & Operational Training
- inVentiv Policies
- Fleet
- inVentiv University (Home Study e-Courses only)
- Pharmaceutical Institute LLC; d/b/a inVentiv Health Learning Solutions, Catalog of e-Courses), in the following categories:
 - i. Therapeutic Essentials (i.e., Disease State e-Courses)
 - ii. Managed Markets Excellence (i.e., Market Access e-Courses)
 - iii. Understanding Pharma (i.e., Industry Background e-Courses)
- Skillsoft Business and Leadership Skills Catalog of e-Courses Only

inVentiv will leverage its internal Learning Management System (LMS) to consolidate the training curriculum and training records which allows for tracking and reporting of certification internally and to client.

3.0 Pre-Launch & Launch Services

- Selling Skills Training; i.e., Aligning Perspectives

EXHIBIT E
COMPENSATION - FIXED FEES, VARIABLE FEES AND PASS-THROUGH COSTS

I. FIXED FEES

(a) Implementation Fee

Client shall pay inVentiv and implementation fee of [*] associated with performance of the Services.

(b) Fixed Monthly Fee

Commencing on the Hire Date, Client shall pay inVentiv a Fixed Monthly Fee as follows:

PERIOD	FIXED MONTHLY FEE
Year One	[*]
Year Two	[*]

inVentiv shall adjust the Fixed Monthly Fee prior to the initial fill of any Account Manager or RBD, prorated for any partial months, according to the Fixed Monthly Fee table outlined in subsection (c)(i), below.

(c) Scale Up

(i) Client may increase the number of inVentiv Account Managers and RBD above the number outlined in Exhibit A (a “Scale Up”) upon written notification to inVentiv. In the event of a Scale Up, Client shall pay to inVentiv an additional Implementation Fee and Fixed Monthly Fee as follows:

Position	Implementation Fee
Per Account Manager	[*]
Per RBD	[*]

Position	Fixed Monthly Fee (Year One)	Fixed Monthly Fee (Year Two)
Per Account Manager	[*]	[*]
Per RBD	[*]	[*]

(ii) The Parties shall meet to agree upon Project Team composition in the event of a Scale Up of greater than [*] Account Managers.

(d) Salary Reconciliation

The parties agree that the Fixed Monthly Fees set forth in Section I (b), above, are based on the annual salary per inVentiv Account Manager of [*] in Year One and [*] in Year Two,

and the annual salary per RBD of [*] in Year One and [*] in Year Two (the “Annual Salary”). inVentiv and Client will reconcile actual salaries and payroll taxes at [*] (pricing assumption), excluding incentive compensation, measured by actual days worked, for each inVentiv Account Manager and RBD in such calendar month against an amount equal to the appropriate percentage of the Annual Salary. The parties agree that the Annual Salary does not include bonuses for the inVentiv Account Managers or RBDs (plus the applicable employer portion of taxes). If any review shows that inVentiv’s actual annual salary per inVentiv Account Manager or RBD is below the Annual Salary, then inVentiv shall issue a credit for the entire amount of such difference to Client. If any review shows that inVentiv’s actual salary per inVentiv Account Manager or RBD is above the Annual Salary, then inVentiv shall bill the difference to Client.

(e) Vacancy Credit

inVentiv agrees to fill vacant territories as requested by Client. inVentiv will continue to invoice Client the amounts set forth above as Fixed Monthly Fee during any such vacancy period. inVentiv will provide a monthly credit to Client, prorated for the number of business days per month that a territory is vacant, for each vacant territory, including leaves of absence lasting longer than [*], until such territory is filled, as set forth in the following table:

	Year One	Year Two
Monthly Vacancy Credit per inVentiv Account Manager	[*]	[*]
Monthly Vacancy Credit per RBD	[*]	[*]

(f) Backfill Recruiting

Client agrees to pay inVentiv a fee of [*] per Account Manager and [*] per RBD for training and recruiting costs associated with any backfill for a vacant territory, provided that Client shall only pay such fee in the event that such territory becomes vacant [*] after the applicable hire date.

II. PASS-THROUGH COSTS

In addition to the Fixed Fees, certain expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost. Pass-through costs include:

- Bonuses for the inVentiv Account Managers (plus applicable employer portion of taxes at [*]), which shall require Client’s prior written approval of both overall the bonus target and achievement plan
- Bonuses for the inVentiv RBDs (plus applicable employer portion of taxes at [*]), which shall require Client’s prior written approval of both overall the bonus target and achievement plan
- Travel expenses (e.g. transportation, lodging, meals, etc.)
- Costs for all meetings, including but not limited to POA Meetings

- Marketing and entertainment costs
- Sales TRx data and any third party data acquisition expenses Manager severance
- Interview expenses (including turnover recruiting)
- Business cards
- Licensing and credentialing expenses
- Shipping, freight, and postage of samples (if incurred)
- Other expenses which have been approved by Client.

III. [*]

- (a) [*]
- (b) [*]
- (c) [*]

IV. INVOICES; BILLING TERMS

The Implementation Fee and [*] of Fixed Monthly Fee shall be paid by Client to inVentiv within [*] of the Effective Date of this Agreement. Commencing on the Hire Date, Client will be billed monthly in advance the amount stated above as the Fixed Monthly Fee. Pass-through Costs will be billed to Client at actual cost as incurred by inVentiv.

Invoices are due in accordance with Section 5 of the MSA.

All invoices shall include the following:

- A/P Email
- A/P Telephone
- A/P Mailing Address
- A/P E-invoice System
- Other Contacts to be Included on Submission of Invoice
- Accountant

Payment to inVentiv may be made by the following method:

- ACH Payment (Preferred Method)
[*]
ACH # [*]
Account # [*]

Advice transmittals should be directed to Art Kopacz — [*] or fax to [*]

In the event Client will be issuing purchase orders for payment of inVentiv invoices, Client shall issue such purchase orders within three (3) days following the execution of this Project Agreement. A purchase order shall include the following:

- PO Number
- PO Contact Name
- PO Contact E-mail
- PO Contact Telephone

Purchase Orders should be directed to Art Kopacz — [*] or fax to [*]

The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Project Agreement provides the terms and conditions governing the relationship between the Parties.

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EXHIBIT F

[*]

Page 1

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EXHIBIT G
HIRING PROFILES

NATIONAL BUSINESS DIRECTOR

Responsibilities:

The National Business Director is primarily responsible for leading, directing and managing all activities of a sales team. The National Business Director is responsible for leading his/her teams to the achievement of established revenue and profit goals by insuring specific individual and team goals are met and expenses are managed in a fiscally responsible manner. The National Business Director will participate in national, regional, and local strategic meetings, as well as, lead meetings with their respective teams.

Key Responsibilities: (Duties may include, but not limited to all or some of the following)

Achieve all performance goals and objectives as established in the client agreement per geographical assignment Achieve revenue target per geographical assignment. Achieve profit target as a percent of revenue. Manage expenses within geographic responsibility. Participate, as requested, in client meetings. Provide communication and motivational programs to insure that members of the sales and client service teams are focused on delivering the expectations of the customer. Reinforce customer focused values. Conduct regularly scheduled meetings with all direct reports Participate, as requested, in internal meetings to update progress and suggest positive solutions to specific issues and/or opportunities Oversee recruiting, staffing, hiring, and training of field sales team Approve all hires Minimize turnover through selection process Provide performance feedback to all direct reports Conduct ongoing discussions and documentation Prepare annual performance appraisal Provide opportunities for personal and professional growth within the sales organization. This includes communication and programs which foster an environment which rewards accomplishment and encourages the advancement and retention of productive employees.

National Business Director Recruiting Profile:

- Minimum Bachelor's Degree Required, MBA preferred
- Minimum of 10+ years pharma sales experience; 7+ years in sales management
- Second line leader/Area level experience but National Sales leadership highly preferred
- Deep experience in preventative vaccines is required
- Candidate should have a strong proven sales leadership, strategic vision, business acumen and influencing skills in order to drive strategic and operational initiatives across the organization
- Documented track record of consistent sales and growth success along with superb account management skills
- History of success building Sales, Marketing, related Commercial Operations teams that achieved/exceeded goals

- Candidate should have broad commercial experience potentially including Sales Operations Management, Sales Training and Marketing Experience
- Proven track record of financial/budget management experience

REGION BUSINESS DIRECTOR

Regional Business Director Position Summary:

In the role of RBD, the individual will formally lead a multi-disciplinary team who are dedicated to mid-size complex healthcare systems as well as at the County Health Departments, FQHCs and the Independent customer types. The RBD's Account Team will be responsible for engaging and supporting the entire account to maximize growth through a structured alignment of resources, coordination of the customer facing teams, and internal stakeholders.

The role will support the Account Manager (AM) team through individual and team coaching and development (both in person and remotely). The individual will also understand customer business models to identify opportunities and develop strategies and tactics across the accounts in their region.

Regional Business Director Recruiting Profile:

- Bachelor's Degree required in Medical Sciences, Marketing, or Business preferred from an accredited institution
- 3+ years of sales management experience required
- Previous industry management experience in sales and/or marketing (account based experience preferred) with a high degree of learning agility
- Vaccine experience highly preferred
- Knowledge of mid-size health systems / group practices, independents, products, therapeutic areas, business and clinical environment preferred. Strong record of high performance and consistent results. Strong coaching and talent development skills
- Strong oral and written communication skills, presentation and influencing skills
- Demonstrated knowledge of promotional objectives both in the mid-size B2B and brand specific, strategies, and tactics
- Knowledge of the changing selling environment (market place selling, payer market segments)
- Ability to drive business results and identify new opportunities and strategies through strategic thinking and business planning.
- Understanding of organization and strategic objectives; Mastery of selling skills including Marketplace and account based selling
- Experience in Matrix Management, Change Advocate
- Heavy travel required ~70%
- Key Competencies: Accountability, Customer Engagement, Customer Discovery, Business Acumen, Executional Effectiveness

ACCOUNT MANAGER

Responsibilities

This opportunity is with our Selling Solutions Commercial Division, which partners with top tier pharmaceutical, medical device and biotechnology companies to develop and execute sales and marketing strategies that deliver. In the role of Account Manager, the individual will be focused on mid-size integrated delivery networks/systems as well as large group practices, County Health Departments, Federally Qualified Health Centers (FQHCs) and Independent customer types. In addition, the Account Manager will provide pull through support for large integrated delivery networks/systems.

The Account Manager will be responsible for engaging and supporting the entire account to maximize growth through a structured alignment of resources, coordination of the customer facing teams, and internal stakeholders. The Account Manager will be responsible for cultivating relationships with key customers and decision makers to influence vaccine brand choice and partner on opportunities to increase Heplisav-B vaccination.

Requirements

- Bachelor's Degree required
- 2-3 years of account management experience required
- Knowledge of Mid-size and large health systems / group practices, independents, products, therapeutic areas, business and clinical environment preferred. Strong record of high performance and consistent results.
- Experience selling to C-Suite and/or key decision makers within complex healthcare delivery networks (highly preferred)
- Ability to drive business results and identify new opportunities and strategies through strategic thinking and business planning.
- Buy and Bill experience preferred
- Vaccine experience highly preferred
- Understanding of organization and strategic objectives; Mastery of selling skills including Marketplace and account based selling
- Demonstrated knowledge of promotional objectives in brand specific strategies and tactics
- Strong oral and written communication skills, presentation and influencing skills
- Knowledge of the changing selling environment (market place selling, payer market segments)
- Experience in Matrix Management, Change Advocate
- Ability to travel and possess a valid driver's license to drive to assigned healthcare accounts, unless otherwise specified
- Heavy travel required ~50%

Key Competencies:

Strategic Account Management, Accountability, Customer Engagement, Customer Discovery, Business Acumen, Executional Effectiveness

**FIRST AMENDMENT TO
PROJECT AGREEMENT
(DETAILING)**

This First Amendment (the “Amendment”) dated October 31, 2017 (the “Effective Date”) is made by and between inVentiv Commercial Services, LLC, with an office at 500 Atrium Drive, Somerset, N.J. 08873 (“inVentiv”) and Dynavax Technologies Corporation (referred to herein as the “Client”). inVentiv and Client may each be referred to herein as a “Party” and, collectively, as the “Parties.”

WITNESSETH:

WHEREAS, inVentiv and Client are parties to a Project Agreement (Detailing) made as of October 31, 2017 (the “Agreement”).

WHEREAS, inVentiv and Client desire to amend the Agreement as set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, it is agreed as follows:

1. Except as provided in this Amendment, the terms and conditions set forth in the Agreement shall remain unaffected by execution of this Amendment. To the extent any provisions or terms set forth in this Amendment conflict with the terms set forth in the Agreement, the terms set forth in this Amendment shall govern and control. Terms not otherwise defined herein, shall have the meanings set forth in the Agreement.

2. Exhibit A, Section I(c), “Deployment Date” is hereby amended to replace the date of March 6, 2017 with **March 6, 2018**.

3. Exhibit E, “Compensation – Fixed Fees, Variable Fees and Pass-Through Costs,” shall be amended as follows:

(i) Section I.(a), “Implementation Fee,” shall be amended to reduce the Implementation Fee to [*].

(ii) Section I.(b), “Fixed Monthly Fee,” shall be amended to delete the Fixed Monthly Fee table in its entirety and replace it with the following:

Period	Fixed Monthly Fee
Year One	[*]
Year Two	[*]

(iii) A new subsection shall be added to Section I. as follows:

(g) Direct Recruiting

inVentiv shall source, screen and recruit [*], or similar roles, for direct hire by Client, as requested (a "Direct Hire"). For each successful placement of a Direct Hire, Client shall pay inVentiv a fee of [*] of the first year base salary, excluding any other compensation including bonuses, equity grants, and benefits, of such Direct Hire. Any cancellations of Direct Hire positions will be subject a cancellation fee outlined in Exhibit A. II(a). Direct recruiting fees shall be invoiced on the next monthly invoice following the placement of the Direct Hire."

(iv) Section II., "Pass-Through Costs," shall be amended to include the following:

- Bonuses for the NBD (plus applicable employer portion of taxes at [*])
- Severance for the NBD ([*] severance in the event of termination prior to the [*] anniversary of the hire date of the NBD; standard inVentiv policy severance thereafter)
- Sign-on bonus for the NBD, as requested by Client.

4. This Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment by exchange of facsimile copies or via pdf file bearing the facsimile signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment by such party. Such facsimile copies and/or pdf versions shall constitute enforceable original documents.

5. The terms of this Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

[SIGNATURE PAGE TO FOLLOW]

WHEREFORE, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

**DYNAVAX TECHNOLOGIES
CORPORATION**

By: /s/ Ryan Spencer
Name: Ryan Spencer
Title: VP, Corporate Strategy
Date: 11-20-17

**INVENTIV COMMERCIAL SERVICES,
LLC**

By: /s/ Theodore Wong
Name: Theodore Wong
Title: VP and CFO
Date: 11/20/17

COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

THIS COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT (this “*Agreement*”) is made effective as of the 22nd day of November, 2013 (the “*Effective Date*”) by and between BAXTER PHARMACEUTICAL SOLUTIONS LLC, a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403 (“*Baxter*”), and DYNVAX TECHNOLOGIES CORPORATION, a Delaware corporation having a principal place of business at 2929 Seventh Street, Suite 100, Berkeley, California 94710 (“*Dynavax*”).

RECITALS

1. Dynavax is engaged in the development, bulk production, formulation, sale and distribution of pharmaceutical products;
2. Baxter is, among other pharmaceutical activities, engaged in the formulation, filling, inspection, labeling and packaging of pharmaceutical products for various biotech and pharmaceutical companies, including competitors of Dynavax and Baxter;
3. Dynavax and Baxter desire to have Baxter purchase certain Components (as defined below) on behalf of Dynavax, formulate, fill, inspect, package, label, and test Product for Dynavax for commercial use.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, Dynavax and Baxter, hereinafter referred to as “*Party*” or “*Parties*”, agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following words and phrases shall have the following meanings:

“*Affiliate*” shall mean any corporation or other business entity directly or indirectly controlled by, controlling, or under common control with a Party or its parent corporation. The term “control” (including, with correlative meaning, the terms “controlled by,” “controlling” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Party, whether through the ownership of voting securities, by contract or otherwise, or such other relationship as, in fact, constitutes actual control.

“*Agreement*” shall be defined in the introductory paragraph.

“*Annual Obligation*” shall be defined in Section 4.3.

“*Batch*” shall mean a specific quantity of a Product comprising a number of Units mutually agreed upon between Dynavax and Baxter, and that (a) is intended to have uniform character and quality within specified limits, and (b) is Produced according to a single manufacturing order during the same cycle of Production.

“**Baxter**” shall be defined in the introductory paragraph.

“**Baxter Property**” shall be defined in Section 13.3.

“**Baxter SOPs**” shall mean Baxter’s standard operating procedures.

“**Bill of Materials**” or “**BOM**” shall mean the listing of Components, part numbers, and relative quantities to be used in the Production of Product.

“**BLA**” shall mean the FDA-required Biologics License Application.

“**Bulk Drug Substance**” or “**BDS**” shall mean the bulk form of the active pharmaceutical ingredient used as the raw material in the Production of Product.

“**Claims**” shall be defined in Section 14.1.

“**Components**” shall mean all components used by Baxter in the Production of Product under this Agreement. Components are listed in the Bill of Materials, such components are identified as the components supplied by Dynavax and components procured by Baxter on behalf of Dynavax (collectively the “**Dynavax Supplied Components**”) and the components supplied by Baxter (the “**Baxter Supplied Components**”).

“**Component Specifications**” shall mean the specifications and testing to be performed for the Components, as set forth in the QCMD.

“**Confidential Information**” shall be defined in Section 18.2.

“**Confidentiality Agreement**” shall be defined in Section 18.2.

“**Contract Requirements**” shall mean at least ninety percent (90%) of Dynavax’s worldwide demand for Product.

“**Contract Year**” shall mean the twelve (12) month period commencing on the date the first Regulatory Approval is obtained by Dynavax and each subsequent twelve (12) month period during the Initial Term and as applicable any renewal term.

“**Current Good Manufacturing Practices**” or “cGMP” shall mean (a) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations (including without limitation 21 CFR 210 and 211), in effect at any time during the Term of this Agreement, for the Production and testing of pharmaceutical materials as applied solely to Products, and (b) the corresponding requirements of each applicable Regulatory Authority.

“**Delivery Date**” shall mean the date that Product is made available by Baxter for pick-up at Baxter’s facility by a common carrier designated by Dynavax.

“**Development Plan**” shall be defined in Section 2.1.

“**Disposition Date**” shall mean Baxter’s disposition of the Executed Batch Record.

“**DMF**” shall be defined in Section 9.6.

2.

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

“**Dynavax**” shall be defined in the introductory paragraph. “**Dynavax Insurance**” shall be defined in Section 15.1. “**Dynavax Property**” shall be defined in Section 13.3.

“**Dynavax’s Intellectual Property**” shall be defined in Section 17.1.

“**Effective Date**” shall be defined in the introductory paragraph.

“**Executed Batch Record**” shall mean the completed batch record (dispositioned by Baxter as released, rejected or aborted) and associated exception reports, and if applicable, a QCMD for each Batch of Product.

“**Expected Yield**” shall be defined in Section 4.5.

“**FDA**” shall mean the United States Food and Drug Administration or any successor entity thereto.

“**FD&C Act**” shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

“**Firm Purchase Order**” shall be defined in Section 4.2.

“**FPPI**” shall be defined in Section 6.2.

“**Imported Goods**” shall be defined in Section 3.7. “**Importer of Record**” shall be defined in Section 3.7. “**Indemnified Parties**” shall be defined in Section 14.1. “**Indemnifying Party**” shall be defined in Section 14.3.

“**Initial Long Range Forecast**” shall be defined in Section 4.1.

“**Initial Term**” shall be defined in Section 8.1. “**Inspection Period**” shall be defined in Section 7.1. “**Invention**” shall be defined in Section 17.2.

“**Launch Material**” shall mean any Product Produced within ninety (90) calendar days of approval of the process validation summary. In addition, Launch Material shall include (a) any Product Produced through formulation and/or filling which will not be immediately inspected, labeled and packaged; such delay may be due to changes to Product, including, but not limited to, a new part number, packaging configuration, country introduction, expiration date change, or change in the filled Unit form, fit or function, and (b) any Product Produced through formulation and/or filling which cannot be immediately released by Baxter due to a failure of Dynavax to provide Baxter with the BDS manufacturer audit report(s) or certificates of completion, license submission or other documentation.

“**Long Range Forecast**” shall be defined in Section 4.1.

“**Losses**” shall be defined in Section 14.1.

“**Master Batch Record**” or “**MBR**” shall mean, with respect to each Presentation of Product to be Produced hereunder, a formal set of instructions for the Production of each Presentation of such Product. The MBR shall be developed and maintained in Baxter’s standard format by Baxter, using Dynavax’s master formula and technical support.

“**Monetary Cap**” shall be defined in Section 13.2.

3.

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“**Party**” or “**Parties**” shall be defined in the Recitals.

“**Permitted Recipients**” shall be defined in Section 18.3.

“**Presentation**” shall mean the specific formula and Components for a Product.

“**Produce**” or “**Production**” shall mean the formulation, filling, packaging, inspecting, labeling, and testing of Product by Baxter as specified in the applicable Master Batch Record or finishing specification sheet.

“**Product**” shall mean formulated Bulk Drug Substance in syringes in final packaged and labeled forms as specified in the Product Addendum and Produced after the first Regulatory Approval therefore.

“**Product Addendum**” shall mean an addendum to this Agreement for each Product and/or Presentation of Product Produced hereunder.

“**Production Price**” shall be defined in Section 5.1.

“**Product Requirements**” shall mean the Product Specifications, Master Batch Record and Baxter SOPs.

“**Product Specifications**” shall mean, with respect to each Product, the specifications and testing to be performed for the BDS, the Product, and/or the stability program that are set forth in Baxter SOPs and the Master Batch Records. The Product Specifications include all tests that Baxter is required to conduct or cause to be conducted as specified in the QCMD. The Product Specifications may be modified from time to time only by a written agreement of Dynavax and Baxter.

“**Project Plan**” shall mean the document(s) containing the parameters for the Production of each Presentation of Product which shall be developed by Baxter and agreed to in writing by Dynavax for each Presentation of Product under this Agreement as set forth in Section 2.2. In addition, the Project Plan may include, without limitation, the Product, Components, Regulatory Authorities, the countries where such Product will be sold, Presentations, Rescheduling Fees and pricing for such Product Produced under this Agreement as set forth in Section 5.1.

“**Purchase Order**” shall mean written orders from Dynavax to Baxter which shall specify (a) the quantity of Product ordered, (b) shipping instructions, (c) requested delivery dates, and (d) delivery destinations.

“**Quality Agreement**” shall have the meaning set forth in Section 2.5.

“**Quality Control Master Document**” or “**QCMD**” shall mean a listing of the analytical testing and corresponding Specifications, to be performed on the Bulk Drug Substance, raw materials and Product. A “*Lot QC Data Packet*,” which includes a Product certificate of analysis containing the same information as the QCMD and other supporting Production documentation, may be provided in lieu of a finished Product QCMD.

“**Regulatory Approval**” shall mean all authorizations by the appropriate Regulatory Authority necessary for commercial sale in a jurisdiction, including without limitation, approval of labeling, price, reimbursement and Production.

4.

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“Regulatory Authority” shall mean those agencies or authorities responsible for regulation of the Products in the United States and such other Regulatory Authorities expressly agreed upon by the Parties in the Quality Agreement. Baxter will have no obligation to Produce Product in compliance with the requirements of a Regulatory Authority not specified in the applicable Quality Agreement.

“Regulatory Plan” shall mean the document(s) containing regulatory services and support for the development and maintenance of regulatory submissions and supporting documentation as set forth in Section 2.4.

“Released Executed Batch Record” shall mean the completed batch record and associated exception reports, and QCMD created for each Batch of Product.

“Reservation Fees” shall be the fees payable by Dynavax for modification of a Firm Purchase Order as set forth in the Project Plan.

“Response Period” shall be defined in Section 7.1.

“SEC” shall be defined in Section 18.5.

“Storage Period” shall be defined in Section 3.8.1.

“Supply Plan” shall be defined in Section 4.1.

“Term” shall be defined in Section 8.1.

“Testing Standards and Procedures” shall mean, with respect to each Product Produced hereunder, the written standards and procedures for evaluating compliance with the applicable Product Specifications, as mutually agreed upon in writing by Dynavax and Baxter, and incorporated in the applicable QCMD.

“Trademarks of Dynavax” shall mean the trademark(s) owned by Dynavax to be affixed on packaging of Product as stated in a Project Plan.

“Twelve Month Rolling Forecast” shall be defined in Section 4.1.

“Unit” shall mean an individually packaged dose of a Product (prefilled syringe) as specified in the applicable Project Plan.

“Yield Rate” shall be defined in Section 4.5.

ARTICLE 2

DEVELOPMENT PLAN, PROJECT PLANS AND REGULATORY PLANS

2.1 Development Plan. If requested by Dynavax, the Parties shall undertake a manufacturing process development project for one or more of the Products to be Produced by Baxter hereunder, consisting of the specific research and development activities agreed upon by the Parties and detailed in a **“Development Plan”**. In no event shall Baxter be required to schedule any development activities with respect to any Product until a Development Plan for such Product has been executed by both Baxter and Dynavax.

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2.2 Project Plan. For each Presentation of Product to be Produced hereunder, the Parties shall agree in writing upon a Project Plan. Baxter shall deliver two (2) copies of each Project Plan to Dynavax prior to the date of initial Production of the applicable Presentation of Product. Dynavax shall either sign such Project Plan and return one (1) copy to Baxter or shall return an amended Project Plan acceptable to Dynavax, in each case within five (5) business days of receipt of such Project Plan from Baxter. If such amended Project Plan is not acceptable to Baxter, then Baxter shall so notify Dynavax within five (5) business days of Baxter's receipt of such amended Project Plan, and the Parties shall promptly meet in order to resolve in good faith any outstanding disagreements with respect to such amended Project Plan. In no event shall Baxter be required to schedule or commence the Production of the Presentation of the applicable Product until a Project Plan for such Presentation of Product has been approved in writing by both Baxter and Dynavax.

2.3 Product Addendum. For each Product and/or Presentation of Product to be Produced by Baxter hereunder, the Parties shall agree in writing upon a Product Addendum. In no event shall Baxter be required to schedule or commence Production of the Presentation of the applicable Product until a Product Addendum for such Presentation of Product has been approved in writing by both Baxter and Dynavax.

2.4 Regulatory Plan. If requested by Dynavax, Baxter shall provide regulatory services in connection with obtaining Regulatory Approval for a Product. Baxter shall deliver to Dynavax two (2) copies of the Regulatory Plan for each Product requested by Dynavax after such Dynavax request and prior to the date that Baxter is to initiate Production of the registration Batches of the applicable Product. Dynavax shall either sign such Regulatory Plan and return one (1) copy to Baxter or shall return an amended Regulatory Plan acceptable to Dynavax, in each case within five (5) business days of receipt of such Regulatory Plan from Baxter. If such amended Regulatory Plan is not acceptable to Baxter, then Baxter shall so notify Dynavax within five (5) business days of Baxter's receipt of such amended Regulatory Plan, and the Parties shall promptly meet in order to resolve in good faith any outstanding disagreements with respect to such amended Regulatory Plan. Baxter shall have no obligation to conduct regulatory services for a Product until the Regulatory Plan for such Product has been agreed upon by the Parties.

2.5 Quality Agreement. The Quality Agreement shall mean that certain Quality Agreement executed by the Parties on October 31, 2013. The Quality Agreement shall allocate the pharmaceutical responsibilities. In no event shall Baxter be required to schedule any Production until a Quality Agreement has been duly signed by both Baxter and Dynavax. Upon execution of the Quality Agreement, the Quality Agreement shall be incorporated by reference as though fully set forth herein.

2.6 Amendment. Each Development Plan, Project Plan, Product Addendum, Regulatory Plan and Quality Agreement may be amended from time to time, as the Parties experience with the development, Production, testing and use of the applicable Product warrants, only upon mutual written agreement of Dynavax and Baxter. In the event that the terms of any Development Plan, Project Plan, Regulatory Plan or Purchase Order are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties. No Development Plan, Project Plan, Regulatory Plan or Purchase Order shall be deemed to amend this Agreement. Upon execution of any Development Plan, Project Plan, or Regulatory Plan, such plan shall be deemed to be incorporated herein by reference and made a part of this Agreement. In the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement will prevail for matters of quality and this Agreement will control for all business, legal, and financial issues.

2.7 Effect of Failure to Execute Plans or Addendum. Failure to execute a Development Plan, Project Plan, or Regulatory Plan with respect to a Product will not relieve either Party of any obligation

accruing with respect to such Product prior to such failure to execute. Dynavax shall reimburse Baxter for all non-cancelable costs incurred by Baxter for work performed and Components ordered with respect to such Product.

ARTICLE 3

PURCHASE AND SUPPLY OF PRODUCT

3.1 Agreement to Purchase and Supply. Pursuant to the terms and conditions of this Agreement, Dynavax shall purchase from Baxter the Contract Requirements of the Product and Baxter shall use good faith efforts to Produce and deliver to Dynavax the Contract Requirements of Product in accordance with Article 4 of this Agreement.

3.2 Reprocessing, Rework or Reproduction. If reprocessing, rework or reproduction is allowed pursuant to Dynavax's regulatory submissions or approved by Dynavax, it shall be performed in accordance with the Quality Agreement and Dynavax shall be responsible for and promptly reimburse Baxter for all costs and expenses incurred in connection with such reprocessing, rework or reproduction.

3.3 Bulk Drug Substance and Component Delivery. Dynavax, at its expense (including without limitation shipping costs), shall supply to Baxter in a timely manner, (a) all Bulk Drug Substances required to satisfy the terms of this Agreement and an applicable certificate of analysis therefore, and (b) all other Dynavax Supplied Components, all to be delivered to Baxter as set forth in the applicable Project Plan for Production of such Product. Except as may specifically be set forth in the Project Plan or QCMD, on receipt of the BDS and Dynavax Supplied Components as set forth above, Baxter's obligations with respect to evaluation of the BDS and Dynavax Supplied Components shall be (i) to review the accompanying certificate of analysis to confirm that the BDS and Dynavax Supplied Components (if applicable) conform with the specifications and (ii) to perform ID testing to confirm the identity of the receiving materials.

3.4 Bulk Drug Substance and Component Delivery Delays. Timely delivery of Dynavax Supplied Components shall mean that the respective Component and the required documents reach Baxter prior to the scheduled manufacturing date of such Product per the timing set forth in the Project Plan. Any delay in delivery of BDS or the Components by the vendor shall not be considered to be a delay by Baxter. Baxter shall have no responsibility for delays in delivery of Product caused by delays in receipt of BDS or Components. Notwithstanding anything in this Agreement to the contrary, in the event that Baxter receives the BDS or Dynavax Supplied Components and associated cGMP documents for Production of Product from Dynavax with less time than requested in the applicable Project Plan, Baxter shall reschedule Production of such Product and may charge Dynavax the applicable Reservation Fee, as specified in Section 4.2.3.

3.5 Purchase of Materials. Baxter shall purchase, at Baxter's expense, all packaging materials listed in the Bill of Materials as Baxter supplied materials, primary container Components and secondary packaging materials specified in the BOM as Baxter supplied and required to Produce the Product. Baxter shall control packaging materials listed in the BOM and shall assist Dynavax with evaluation and purchase of modified materials in the event that Dynavax requests a change in Presentation. Baxter shall not initiate any changes to materials without written approval from Dynavax.

3.6 Baxter Supplied Components. Baxter will purchase the Baxter Supplied Components in quantities sufficient to meet Dynavax's Purchase Orders for Product consistent with Article 4. Baxter will

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invoice Dynavax for the primary packaging Components as specified in Section 5.4 and Exhibit C upon receipt of such Components. Dynavax will reimburse Baxter for these primary packaging Components within thirty (30) calendar days after delivery of an invoice therefore to Dynavax.

3.7 Importer of Record. In the event any material or equipment to be supplied by Dynavax, including without limitation Dynavax Supplied Components and BDS, is imported into the United States for delivery to Baxter (the “**Imported Goods**”), such Imported Goods shall be imported DDP Bloomington, IN (Incoterms, 2010). Dynavax or its Affiliate shall be the “**Importer of Record**” of such Imported Goods. As the Importer of Record, Dynavax shall be responsible for all aspects of the Imported Goods including, without limitation (a) customs and other regulatory clearance of Imported Goods, (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Imported Goods, and (c) keeping all records, documents, correspondence and tracking information required by applicable laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods.

3.8 Storage.

3.8.1 Product Storage. Baxter will store Product free of charge for [*] after the Disposition Date (“**Storage Period**”). Baxter will not be required to store Product longer than such Storage Period without Baxter’s prior written consent and Dynavax’s agreement to reimburse Baxter for all costs incurred in connection with such storage. The storage fees are set forth in the Project Plan. Baxter shall be permitted to store Product, BDS and Materials in third party storage facilities upon the prior approval of Dynavax.

3.8.2 BDS and Component Storage. In no event shall Baxter be required to store quantities of BDS and Components more than required to Produce a [*] supply of Product as calculated using the Twelve Month Rolling Forecast without the prior written consent of Baxter and Dynavax’s agreement to reimburse Baxter for all costs incurred in connection with such storage.

ARTICLE 4

FORECASTS, ORDERS, AND CAPACITY

4.1 Forecasts, Order Limits, and Supply Plan.

4.1.1 Long Range Forecast. Within thirty (30) days from the Effective Date of this Agreement and prior to June 1 of each year thereafter, Dynavax will provide to Baxter in writing an annual forecast for the next five (5) calendar years during the Term of Dynavax’s estimated Contract Requirements for Product (the “**Long Range Forecast**”). The initial Long Range Forecast shall be included in the Product Addendum (pursuant to Exhibit D) and shall be considered the “**Initial Long Range Forecast**”. Baxter specifically agrees that such Long Range Forecasts submitted by Dynavax will be for general planning purposes only, and shall not be binding on Dynavax or Baxter.

4.1.2 Twelve Month Rolling Forecast. Commencing one month after the date of the first Regulatory Approval of Product, and on each December 1st, March 1st, June 1st and September 1st thereafter during the Term, Dynavax will provide to Baxter in writing a “**Twelve Month Rolling Forecast**” for the following twelve month period (i.e. the Twelve Month Rolling Forecast submitted December 1st will be for the twelve month period beginning January 1st the Twelve Month Rolling Forecast submitted March 1st will be for the twelve month period beginning April 1st, and so on). The total quantity of Batches of the

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first [*] of the Twelve Month Rolling Forecast shall be considered 100% binding. The total quantity of Batches of the [*] of the Twelve Month Rolling Forecast shall be considered [*] binding. Should the quantity forecasted in the [*] be an odd number of Batches, then the binding forecast shall be [*] of the number of Batches forecasted. The quantity of the remaining [*] of the Twelve Month Rolling Forecast shall be for general planning purposes only, and shall not be binding on Dynavax or Baxter.

4.1.3 Supply Plan. Baxter will confirm each Twelve Month Rolling Forecast within twenty-one (21) days of receipt of the Twelve Month Rolling Forecast and supply Dynavax with a corresponding supply plan (the “**Supply Plan**”) for such twelve month period. In the case that a supply plan cannot be agreed between the two Parties, Dynavax and Baxter shall use good faith efforts to come to an agreed plan. During this time, Baxter agrees to supply, at a minimum, the quantities agreed in the most recently agreed Supply Plan.

4.1.4 Failure to Submit Rolling Forecast. In addition to any and all other remedies available to Baxter under this Agreement, in the event that Dynavax fails to provide a suitable Twelve Month Rolling Forecast prior to the tenth (10th) day of the month in which such Forecast is due as provided in Section 4.1.2, Baxter may, in its discretion, rely on the most recent forecast previously submitted by Dynavax in lieu of such late and/or deficient forecast. Any previous forecast(s) so relied upon by Baxter under this Section 4.1.4 shall be deemed binding upon Dynavax to the full extent provided under this Article 4.

4.2 Purchase Orders.

4.2.1 General Terms. Dynavax shall submit Purchase Orders to Baxter covering Dynavax’s purchases of Product pursuant to this Agreement and specifying project code, Units and delivery date. For the avoidance of doubt, supply of Product under this Agreement shall not be subject to the terms and conditions contained on any Purchase Order and/or acceptance thereof except insofar as any such Purchase Order and/or acceptance establishes the quantity and requested delivery dates for such Product.

4.2.2 Order Lead Time. Dynavax shall not, without the written consent of Baxter, designate a Delivery Date in a Purchase Order earlier than [*] from the date Dynavax submits the Purchase Order. Baxter shall provide a confirmation of receipt of each Purchase Order setting forth the Delivery Date that Baxter will meet. Upon sending the confirmation, such Purchase Order shall become a “**Firm Purchase Order**”. If Baxter is unable to meet the delivery date specified by Dynavax, except when caused by Dynavax’s delay in delivery of BDS and/or Dynavax Supplied Components, Baxter shall so notify Dynavax and Baxter will use commercially reasonable efforts to provide to Dynavax an alternative Delivery Date which shall not be more than [*] later than the initial delivery date designated by Dynavax in its Purchase Order.

4.2.3 Purchase Order Cancellation. In the event that Dynavax cancels a Batch(es) of Product in a Firm Purchase Order or otherwise modifies a Firm Purchase Order less than [*] prior to the Delivery Date, and as a result thereof Baxter, if after using best efforts to substitute a production run for another Baxter client or for a Baxter Affiliate, is left with an open production slot, Dynavax shall pay, as liquidated damages and not as a penalty, the Reservation Fee set forth in the table below unless expressly

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agreed to otherwise in the Project Plan. To the extent of any conflict between Purchase Orders submitted by Dynavax and this Agreement, this Agreement shall control.

Timing	Reservation Fee per Cancelled or Modified Batch
Cancellation or modification of a Firm Purchase Order [*] days or more from the Delivery Date	0
Cancellation or modification of a Firm Purchase Order [*] days but not less than [*] days from the Delivery Date	[*]% of the Production Price of Product
Cancellation or modification of a Firm Purchase Order [*] days but not less than [*] days from the Delivery Date	[*]% of the Production Price of Product
Cancellation or modification of a Firm Purchase Order [*] days or less from the Delivery Date	[*]% of the Production Price of Product

4.3 Annual Obligation. Subject to Section 4.4, Dynavax shall be obligated to purchase from Baxter Dynavax’s Contract Requirements of Product in each calendar year during the Term of this Agreement as specified in the Product Addendum (the “**Annual Obligation**”), which Annual Obligation shall be prorated for any partial calendar year. Within thirty (30) calendar days after the end of each calendar year, Dynavax will provide Baxter with a signed affidavit, along with supporting documentation, that Dynavax met or exceeded its Annual Obligation in the previous calendar year. In the event Baxter disputes the data provided by Dynavax, Baxter will provide supporting data to Dynavax and the Parties will in good faith work together to reach agreement on the volume of Product representing Dynavax’s Contract Requirements during the applicable calendar year. In the event Dynavax does not meet or exceed its Annual Obligation in any calendar year, Dynavax shall pay to Baxter the difference between the aggregate Production Price of Product actually purchased pursuant to Sections 4.1 and 4.2 by Dynavax and the aggregate Production Price of the Annual Obligation of Product, with such payment due within thirty (30) days of such determination.

4.4 Order Maximum. Notwithstanding anything in this Article 4 to the contrary, in any calendar year during the Term of this Agreement, in no event shall Baxter be obligated to Produce more Product than specified in the Product Addendum. If changes (increases or decreases) in the annual order volume require changes in equipment and/or process, Dynavax will cover the costs for such changes.

4.5 Yield

4.5.1 Yield Rate Calculation. There shall be no minimum yield requirement on the first [*] Batches of commercial Product Produced hereunder. The yield from these first [*] Batches will be used to calculate the Expected Yield (as defined below) for Product. From the data collected, the Parties will calculate the yield rate which will equal the mean of the yield of the first twenty Batches of conforming Product Produced after the completion of the process validation Batches, including without limitation, Product samples such as release samples, stability samples, etc. (the “Yield Rate”).

4.5.2 Expected Yield Requirement and Reconciliation. Upon calculation of the Yield Rate, the aggregate average yield of Batches of Product supplied to Dynavax by Baxter during each calendar year shall have a quantity equal to or greater than [*] of the Yield Rate calculated above (“**Expected Yield**”). Within sixty (60) days after the end of each calendar year, the Parties will calculate the actual aggregate average yield of Product Produced during the previous calendar year. If the actual aggregate average yield of Product in any calendar year is less than the Expected Yield, Baxter shall reimburse

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Dynavax the difference of the cost of the Dynavax Supplied Components between the Expected Yield and the actual quantity supplied, such reimbursement not to exceed the Production Price of a Unit for each Unit short of the Expected Yield.

ARTICLE 5

PRICE

5.1 Product Production Price. The price to be paid by Dynavax for the Production of Product (the “**Production Price**”) shall be set forth in the Product Addendum.

5.2 Regulatory Services Price. The price to be paid by Dynavax for regulatory services shall be set forth in the Regulatory Plan.

5.3 Production Price Adjustment. Upon the first anniversary of the Effective Date of this Agreement and on each anniversary thereafter, Baxter may increase the Production Price of such Product by a percentage which may not exceed the percentage change in the U.S. PPI Commodity Data (Producer Price Index Commodity Data) for the previous twelve (12) months.

5.4 Components. Based upon the Twelve Month Rolling Forecast, Baxter and Dynavax shall develop a joint strategy for the purchase of primary packaging Components (syringe, stopper and plunger rod). Baxter shall not be liable for delays in receipt of such Components. Upon receipt of the primary packaging Components, Baxter will invoice Dynavax for such Components. Such invoice will include a one percent (1%) handling fee. Dynavax shall pay for such Components within thirty (30) calendar days of the invoice date. Title to Dynavax Supplied Components, including those primary packaging Components procured by Baxter on behalf of Dynavax, shall at all times belong to and remain in Dynavax; provided, however, that Baxter shall retain a security interest in such primary packaging Components until receipt of payment from Dynavax. Baxter will provide Dynavax with inventory reports for Dynavax Supplied Components and Product on hand at Baxter in a format and on timing that is agreeable to both Parties.

ARTICLE 6

SHIPMENT AND INVOICING

6.1 Delivery Terms. Product shall be delivered to Dynavax, or to a location designated by Dynavax in the Purchase Order, EXW (Incoterms, 2010) Baxter’s facility in Bloomington, Indiana, freight collect, by a common carrier designated by Dynavax in the Purchase Order, at Dynavax’s expense; provided, however, Baxter shall be responsible for the loading of the Product on departure and shall bear all costs of such loading.

6.2 Subsequent Export. Dynavax agrees and represents that Dynavax is the owner of the goods that are consigned to Baxter for contract manufacturing services and warrants that Dynavax is responsible for any subsequent export or re-export and will comply with all applicable U.S. laws and regulations relating to the export or re-export, including the prohibition against unlawful transshipments. Further, where such goods are destined for export or re-export, Dynavax agrees and accepts that it is the Foreign Principal Party in Interest (“**FPPI**”) and warrants that as the FPPI, it will duly authorize and retain a U.S. agent who will act on its behalf, assuming all attendant responsibilities associated with the export or re-export, including obtaining any necessary export licenses, pursuant to 15 C.F.R. §758.3. The Dynavax’s responsibilities as FPPI include, but are not limited to, cooperating with its U.S. agent in providing the U.S.

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government with a detailed description and accurate valuation and classification of the goods, bills of lading, and all other required documentation. Dynavax further agrees to defend Baxter against any action, civil or criminal, private or public, in connection with the subsequent export or re-export by Dynavax of the goods.

6.3 Payment Terms. The following invoicing and payment terms apply:

Status	Invoice Date	Payment Due
Process Validation Batches	[*]% of manufacturing price at Baxter's disposition of the manufacturing (filling portion) batch record [*]% of finishing price at Baxter's disposition of the finishing (labeling and packaging portion) batch record	Invoice date + [*] days*
Launch Material	[*]% of manufacturing price at Baxter's disposition of the manufacturing (filling portion) batch record [*]% of finishing price at Baxter's disposition of the finishing (labeling and packaging portion) batch record	Invoice date + [*] days*
On-going Commercial	Baxter's Disposition Date	Invoice date + [*] days*
Regulatory Services	Monthly	Invoice date + [*] days*
Development Services	As set forth in Development Plan	Invoice date + [*] days*

* All days specified above are calendar days.

Notwithstanding the foregoing, in the event Baxter begins Production of a Batch of Product and is unable to release such Batch due to delays by Dynavax, Baxter may invoice Dynavax for one hundred percent (100%) of the manufacturing portion of the Production Price thirty (30) calendar days from the date of Baxter's disposition of the manufacturing (filling portion) batch record of such Batch of Product. For purposes of example only, delays by Dynavax may include, but are not limited to, failure to provide approval for artwork, failure to approve bills of materials or finishing records, and failure to designate a packaging configuration. The finishing portion of the Production Price will be invoiced and reconciled at the time of disposition of the finishing operations and provision of the Executed Batch Record to Dynavax.

Payments shall be made in U.S. dollars. Each invoice shall be payable by Dynavax in accordance with the terms noted above. Any payment due under this Agreement not received within the times noted above shall incur finance charges at the lesser of (a) the maximum rate permitted by law, or (b) one and a half percent (1.5%) per month on the outstanding balance.

6.4 Default in Payment Obligations. In addition to all other remedies available to Baxter in the event of a Dynavax default, if Dynavax fails to make payments as required hereunder and such failure continues for thirty (30) days, Baxter may refuse all further Purchase Orders, refuse to Produce any Product until Dynavax's account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of Product until Dynavax provides assurance of performance reasonably satisfactory to Baxter, and/or take other reasonable means as Baxter may determine.

ARTICLE 7

ACCEPTANCE OF PRODUCT

7.1 Product Conformity. Within [*] from the date of shipment of samples of Product or the release of the Released Executed Batch Record to Dynavax, whichever is later (the "**Inspection Period**"), Dynavax will determine whether such Batch of Product was Produced in accordance with the Product Requirements and accept or reject such Batch of Product for non-conformance to the Product Requirements; provided, however, that Dynavax shall have the right to revoke acceptance if, within [*] of receipt of the Batch, Dynavax discovers a defect not reasonably discoverable at the time of delivery. If Dynavax fails to notify Baxter within the applicable time periods that the Batch of Product does not conform to the Product Requirements, Dynavax shall be deemed to have accepted the Product and waived its right to revoke acceptance. If Dynavax believes a Batch does not conform to the Product Requirements, it shall notify Baxter as set forth in Section 7.1.1.

7.1.1 If Baxter released a Batch of Product and Dynavax believes such Batch does not conform to the Product Requirements, it will provide to Baxter a detailed written explanation of the non-conformity within the Inspection Period. Upon receipt of such notice, Baxter will investigate such alleged non-conformity and, (a) if Baxter agrees such Batch of Product is non-conforming, deliver to Dynavax a corrective action plan within thirty (30) calendar days after receipt of Dynavax's written notice of non-conformity, or such additional time as is reasonably required if such investigation or plan requires data from sources other than Dynavax or Baxter (the "**Response Period**"), or (b) if Baxter disagrees that such Batch of Product is non-conforming, Baxter will so notify Dynavax in writing within the Response Period.

7.1.2 If the Parties dispute whether the Batch of Product is non-conforming, the dispute will be handled in accordance with Section 9.1.1 of the Quality Agreement. The costs of the laboratory or consultant referred to in the Quality Agreement are to be borne by the Party whose determination was incorrect.

7.1.3 In the event Baxter does not release a Batch of Product due to a nonconformity, it shall so notify Dynavax in accordance with the Quality Agreement.

7.2 Remedies for Non-Conforming Product. If a Batch of Product is non-conforming as a result of Baxter's negligence or willful misconduct, then Baxter will, to the extent of its negligence or willful misconduct, (a) reimburse Dynavax for its actual cost of the Bulk Drug Substance and Dynavax Supplied Components needed for its replacement Product, which reimbursement shall not exceed [*] of

such nonconforming Batch and, [*], (b) if Dynavax has paid for such non-conforming Batch, either [*] or [*] or (c) if Dynavax has not paid for the nonconforming Batch, Baxter will not invoice for the nonconforming Batch.

7.3 Remedies for Non-Conforming Stability/Process Validation Batches. Notwithstanding the foregoing Section 7.2, if a stability Batch or process validation Batch is nonconforming as a result of Baxter's negligence or willful misconduct, then Baxter will, to the extent of its negligence or willful misconduct, (a) reimburse Dynavax for its actual cost of the Bulk Drug Substance and Dynavax Supplied Components needed for its replacement Product, which reimbursement will not exceed [*] of such non-conforming stability Batch or process validation Batch [*], (b) if Dynavax has paid for such non-conforming Batch, [*] or [*] or (c) if Dynavax has not paid for the non-conforming Batch, Baxter will not invoice for the nonconforming Batch.

7.4 Escalation Process. In the event Baxter and Dynavax disagree as to whether a Batch of Product is non-conforming as a result of Baxter's negligence or willful misconduct ("**Disagreement**"), and such Disagreement is not resolved by the Parties for a period of sixty (60) days of the Parties first consideration, the Disagreement will escalate to the Parties' executive management for resolution (for Baxter that shall mean the Global Franchise Head or his/ her designee and for Dynavax that shall mean SVP Operations or his / her designee). If the executive management cannot resolve such Disagreement within thirty (30) days of their first consideration, then, at any time after such thirty (30) day period, either Party may pursue any other available legal or equitable remedy.

7.5 Non-conforming Bulk Drug Substance. If a Batch of Product is not released by Baxter or is rejected by Dynavax, and such non-conformity is the result of non-conforming Bulk Drug Substance or Dynavax Supplied Components, then Baxter will have no liability for such nonconforming Batch, except as set forth in Sections 7.2 or 7.3.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term. This Agreement shall commence on the Effective Date and shall continue until the last day of the sixth (6th) Contract Year (the "**Initial Term**"), unless earlier terminated in accordance with Sections 8.2 or 8.3 of this Agreement. This Agreement may be renewed for [*] renewal term(s), if agreed in writing by both Dynavax and Baxter at least [*] prior to the expiration of the Initial Term or a renewal term, as the case may be. The Initial Term as may be extended is referred to herein as the "**Term**".

8.2 Termination for Breach. Either Party may terminate this Agreement upon the material breach of any provision of this Agreement by the other Party if such breach is not cured by the breaching Party within ten (10) calendar days for monetary defaults, and forty-five(45) calendar days for non-monetary defaults (or such additional time as is reasonably necessary to cure such nonmonetary default after receipt by the breaching Party of written notice of default). At the option of the non-breaching Party, such termination may be with respect to the entire Agreement, or only with respect to the Product which is subject to the breach.

8.3 Termination for Financial Matters. Either Party may terminate this Agreement immediately by giving the other Party written notice thereof in the event such other Party shall become insolvent or unable to pay its debts when due, or in the event that proceedings are commenced against, or voluntarily by, such Party relating to its bankruptcy or insolvency.

14.

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

8.4 Additional Rights and Remedies. Subject to Section 1.3.1, termination under this Article 8 shall be in addition to the other rights and remedies of the terminating Party as specified herein.

8.5 Non-cancelable Costs and Expenses. In the event of the termination or expiration of this Agreement, except by Dynavax as a result of a breach by Baxter under Section 8.2, Dynavax will (a) reimburse Baxter for all materials, Components, and equipment ordered prior to termination and not cancelable at no cost to Baxter, and (b) pay Baxter for any outstanding Firm Purchase Orders. In addition, in the event of termination or expiration for any reason, Dynavax will pay [*] for (a) all work-in-process commenced by Baxter and (b) all finished Product Produced prior to expiration or termination. Baxter will ship such materials to Dynavax pursuant to Section 6.1 at Dynavax's cost and per Dynavax's instructions. Dynavax will make payments for all expenses described in this Section 8.5, no later than thirty (30) calendar days from the invoice date.

8.6 Survival. Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason shall be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement, subject to Article 13. The provisions of Articles 8, 9.3, 12, 13, 14, 15, 16, 17 and 18 hereof shall survive expiration or termination of this Agreement. Termination of this Agreement for any reason shall not relieve any Party of any obligations accruing prior to such termination.

ARTICLE 9

PRODUCTION OF PRODUCT

9.1 Audits.

9.1.1 Quality Audits. Dynavax, upon prior written notice and on dates and times agreed by the Parties, shall have the right to inspect, [*], Baxter batch records and the portions of Baxter's facilities used for Production of Product. In addition, Dynavax shall audit Baxter SOPs. If Dynavax chooses to audit more than one (1) time in a calendar year, unless such additional audit is for cause, Dynavax will reimburse Baxter for its reasonable expenses incurred in hosting the audit. As used herein, an audit shall be "for cause" if Product has repeatedly failed to conform to the Product Requirements, a Regulatory Authority has found that Baxter failed to comply with applicable laws in the Production of Product, or a recall of Product has occurred. All audited data will be treated as Confidential Information of the Party that owns such information.

9.1.2 Other Audits. Except as provided in Section 9.1.1, any audit shall be at the expense of Dynavax and the prior written consent of Baxter, which consent will not be unreasonably withheld.

9.2 Testing. Baxter shall test, or cause to be tested by third party testing facilities audited by Baxter, in accordance with the Product Specifications, each Batch of Product before delivery to Dynavax. A certificate of analysis for each Batch of Product delivered to Dynavax shall be contained in the Quality Control Master Document and shall set forth the items tested by Baxter, specifications, and test results. Dynavax cannot release a Batch of Product that Baxter rejects. As required by the FDA, Dynavax shall assume full responsibility for final release of each Batch of the Product.

9.3 Stability Testing. At Dynavax's expense, Dynavax or a party selected by Dynavax shall perform all stability testing required to be performed on clinical, development, and/or Production Batches

of Product. If performed by Baxter, such testing shall be performed in accordance with the procedures set out in the Product-specific Baxter SOPs for the stability protocol and the Project Plan. If Baxter is not performing stability testing, then Baxter requires at a minimum that Baxter perform the sterility testing as part of the stability program. Such stability protocol shall contain a listing of the analytical testing and corresponding Product Specifications, to be performed on the Product in connection with the stability testing program under 21 CFR § 166.

9.4 Permits and Licenses. Dynavax shall have sole responsibility, at its expense, for obtaining, maintaining, updating and remaining in compliance with all permits, licenses and other authorizations during the Term of this Agreement, which are necessary or required under federal, state, and local law, rules and regulations and which are applicable to the Production, use, and sale of Product. Baxter shall be responsible, at its expense, to obtain and maintain all generally required permits and licenses applicable to production of pharmaceutical products generally which are required for Baxter to carry out its development, regulatory and Production obligations hereunder.

9.5 Regulatory Requirements. Each Party promptly shall notify the other of new regulatory requirements of which it becomes aware which are relevant to the Production of a Product under this Agreement and which are required by the FDA, any other applicable Regulatory Authority or other applicable laws or governmental regulations, and shall confer with each other with respect to the best means to comply with such requirements. Baxter shall have no obligation to Produce Product in compliance with the requirements of a Regulatory Authority not explicitly specified in the Quality Agreement. Dynavax shall supply to Baxter a copy of its license submission prior to Baxter's Production of Product.

9.6 Drug Master File. Baxter shall file and maintain the appropriate Drug Master File (the "**DMF**") and related reference applications (e.g. Site Master File) for its Production of each Product hereunder in accordance with 21 CFR 314.420, as may be amended from time to time, at Baxter's expense.

9.7 Annual Quality Review. Annual Quality Review will be conducted in accordance with the Quality Agreement. If Dynavax requests Baxter to perform such quality review, such review will be conducted at Dynavax's cost and expense.

9.8 Customer Complaints and Adverse Events. All customer complaints will be managed in accordance with the Quality Agreement.

9.9 Changes in Manufacturing.

9.9.1 Changes to Master Batch Records and Product Specifications. Baxter agrees to inform Dynavax within fifteen (15) calendar days of the result of any regulatory development or changes to Product-specific Baxter SOPs that materially affect the Production of the Product. Baxter shall notify Dynavax of and require written approval from Dynavax for material changes to Product-specific Master Batch Records and Product Specifications prior to the Production of subsequent Batches of Product.

9.9.2 Product-Specific Changes. If facility, equipment, process or system changes are required of Baxter as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply solely to the Production and supply of one or more Products, then Dynavax

and Baxter will review such requirements and agree in writing to such regulatory changes, and Dynavax shall bear [*] of the reasonable costs thereof.

9.9.3 General Changes. If such regulatory changes apply generally to one or more Products as well as to other products produced by Baxter for itself or for third parties, Baxter will cover the cost of such general regulatory changes; provided, however, such costs do not exceed [*]. In the event the cost of any such regulatory change exceeds [*], Baxter will notify Dynavax so the Parties can further discuss, and if Baxter determines, in its sole discretion, not to proceed with the regulatory change, either Party may terminate this Agreement upon one hundred eighty (180) days written notice to the other Party.

9.10 Equipment Expenses. If Baxter is required to obtain specialized equipment in order to Produce Product for Dynavax, the price of such equipment shall be paid by Dynavax. Baxter shall advise Dynavax of the specialized equipment required and the estimated price associated with the purchase and installation of such equipment. Dynavax shall be invoiced for all approved costs as specified in the Project Plan.

9.11 Ownership of Equipment. Upon termination or expiration of this Agreement, Dynavax shall either (i) take possession of the specialized equipment paid for by Dynavax at Dynavax's expense, or (ii) offer Baxter the option to purchase such equipment at a price to be negotiated at the time of sale.

ARTICLE 10

REGULATORY

10.1 Regulatory Approvals. Dynavax will diligently pursue Regulatory Approval of marketing licenses for each Product Produced by Baxter hereunder. Dynavax will advise Baxter of document requirements in support of BLA and similar applications required of foreign governments and agencies including amendments, license applications, supplements and maintenance of such. Baxter will provide documents and assist Dynavax in preparation of submissions to Regulatory Authorities (both U.S and foreign) designated by Dynavax in support of Dynavax's BLA and similar applications required of foreign governments and licenses. All regulatory submission preparation and maintenance performed by Baxter for Dynavax shall be specified in the Regulatory Plan. Prior to submission to the Regulatory Authority, Dynavax will, at Dynavax's option, provide Baxter with a copy of the relevant portions of the CMC section for review and comment. A final copy of the relevant CMC section will be provided by Dynavax to Baxter upon submission to the Regulatory Authority. Upon Regulatory Approval, Dynavax will notify Baxter within two (2) calendar days of such approval and the anticipated date of Product launch to the market.

ARTICLE 11

TRADEMARKS

11.1 Dynavax grants to Baxter a non-exclusive, royalty free license to use Trademarks of Dynavax for the sole purpose of allowing Baxter to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part.

11.2 Dynavax shall be solely responsible for selecting, registering and enforcing Trademarks of Dynavax used to identify the Product; and, except as set forth in Section 11.1, shall have sole and exclusive rights in such Trademarks of Dynavax.

ARTICLE 12

REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations. Each Party hereby represents and warrants to the other Party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

12.2 Baxter Warranty. Baxter represents and warrants that Product shall be Produced in accordance with applicable cGMPs. Baxter shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of BDS or Product or with respect to the labeling of Product. Baxter makes no representation or warranty with respect to the sale, marketing, distribution or use of the BDS, Product or to printed materials specified by Dynavax or its consignee.

12.3 Disclaimer of Warranties. Except for those warranties set forth in Sections 12.1 and 12.2 of this Agreement, Baxter makes no warranties, written, oral, express or implied, with respect to Product or the Production of Product. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY BAXTER. NO WARRANTIES OF BAXTER MAY BE CHANGED EXCEPT BY A DULY AUTHORIZED REPRESENTATIVE OF BAXTER. Dynavax accepts Product subject to the terms hereof.

12.4 Dynavax Warranties. Dynavax warrants that (a) it has the right to give Baxter any information provided by Dynavax hereunder, and that Baxter has the right to use such information for the Production of Product, (b) Dynavax has no knowledge of any (i) patents or other intellectual property rights that would be infringed by Baxter's Production of Product under this Agreement, or (ii) proprietary rights of third parties which would be violated by Baxter's performance hereunder, and (c) it shall comply with all applicable laws, rules and regulations. Dynavax warrants that the BDS provided to Baxter hereunder will (1) conform to the BDS specifications and (2) not be adulterated or misbranded within the meaning of the FD&C Act.

ARTICLE 13

EXCLUSIVE REMEDIES, LIMITATION OF LIABILITY AND RISK OF LOSS

13.1 Exclusive Remedies. Dynavax's right to recover damages, losses or expenses from Baxter, and Baxter's liability under this Agreement, is limited to the amounts set forth in the applicable sections of this Agreement. All claims by Dynavax under this Agreement (except claims seeking indemnity) shall be brought no later than two (2) years after the occurrence of the event giving rise to such claim; otherwise, such claim shall be deemed waived.

13.2 Limitation of Liability. Except to the extent recoverable under Article 14, under no circumstances shall either Party be liable for incidental, special, consequential, punitive, exemplary or indirect damages, including but not limited to, lost profits, or except as specifically set forth in this Agreement, loss, damage or destruction of the BDS or Dynavax Supplied Components, the cost of cover or recall costs, whether such claims are founded in tort or contract, and even if the other Party asserts or

18.

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

establishes a failure of the essential purpose of any limited remedy provided in this Agreement. To the extent permitted under applicable laws, under no circumstances shall Baxter's aggregate liability under this Agreement, including but not limited to third party claims, exceed the aggregate amount paid to Baxter under this Agreement (the "**Monetary Cap**").

13.3 Risk of Loss. All Baxter Supplied Components and equipment used by Baxter in the Production of Product (collectively, the "**Baxter Property**") shall at all times remain the property of Baxter and Baxter assumes risk of loss for the Baxter Supplied Components until delivery of Product to a common carrier as specified under Section 6.1. Dynavax assumes risk of loss for Dynavax Supplied Components, Dynavax equipment, all BDS supplied by Dynavax, and all Product (collectively, "**Dynavax Property**"), except in the case of Baxter's negligence or willful misconduct; in which case, Baxter will, to the extent of its negligence or willful misconduct, reimburse Dynavax for the actual cost of such loss not to exceed one hundred percent (100%) of the Production Price of the Product affected by such loss (which, in the case of loss of BDS or Dynavax Supplied Components shall be calculated based on the quantity of Product that could have been Produced using such BDS or Dynavax Supplied Components). Notwithstanding anything herein to the contrary, Baxter shall have no liability for, and Dynavax releases all claims against Baxter arising out of, any damage or loss to Product, BDS or Components arising out of, or in connection with, the storage of Product, BDS or Components after the Storage Period.

ARTICLE 14

INDEMNIFICATION

14.1 Dynavax Indemnification. Dynavax shall indemnify, defend and hold harmless Baxter and its Affiliates and any of their respective directors, officers, employees, subcontractors and agents (collectively, the "**Indemnified Parties**") from and against any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees) ("**Losses**") to, and claims, demands, actions, suits by a third party (collectively, "**Claims**"), including claims of property damage, death or personal injury for which the Indemnified Parties otherwise would be strictly liable, in connection with pending or threatened litigation or other proceedings, which arise out of or relate to any one of the following:

- (a) Dynavax's storage, promotion, labeling, marketing, distribution, use or sale of Product;
- (b) Baxter's use of the BDS;
- (c) Dynavax's negligence or willful misconduct;
- (d) Components;
- (e) Dynavax's breach of any covenant, representation or warranty contained in this Agreement; or
- (f) the use, sale, Production, marketing or distribution of BDS or Product by Baxter or Dynavax violates the patent, trademark, copyright or other proprietary rights of any third party.

14.2 Baxter Indemnification. Baxter shall indemnify, defend and hold harmless Dynavax and its Affiliates and any of their respective directors, officers, employees, subcontractors and agents from and against any and all Losses to, and Claims by a third party, in connection with pending or threatened litigation or other proceedings, to the extent resulting from Baxter's negligence or willful misconduct. Baxter's liability under this Section 14.2 shall be subject to the Monetary Cap.

14.3 Indemnitee Obligations. Any Party seeking indemnification hereunder (a) shall give prompt written notice to the other Party (the "**Indemnifying Party**") of any claim for which indemnification is sought (b) shall permit the indemnifying Party to assume full responsibility to investigate, prepare for and defend against the Claim, (c) shall reasonably assist the Indemnifying Party, at the Indemnifying Party's reasonable expense in the investigation of, preparation for the defense of such Claim, and (d) shall not compromise or settle such Claim without the Indemnifying Party's prior written consent.

ARTICLE 15

INSURANCE

15.1 Dynavax Insurance. Dynavax shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of Product Produced under this Agreement, appropriate insurance coverage for the type of liability that may occur under this Agreement; provided, however, Dynavax shall procure and maintain no less than [*] in Product Liability coverage prior to U.S. Regulatory Approval of Product and no less than [*] in Product Liability coverage upon U.S. Regulatory Approval of Product. All such coverage shall be with an insurance carrier with an A.M. Best rating of A-VII or better. Dynavax promptly shall deliver a certificate of Dynavax Insurance to Baxter evidencing such coverage. If Dynavax fails to furnish such certificates, or if at any time during the Term of this Agreement Baxter is notified of the cancellation or lapse of the Dynavax Insurance, and Dynavax fails to rectify the same within ten (10) calendar days after notice from Baxter, in addition to all other remedies available to Baxter hereunder, Baxter may terminate this Agreement. Any deductible and/or self-insurance retention shall be the sole responsibility of Dynavax.

15.2 Baxter Insurance. Baxter is, and will during the Term of this Agreement remain, self-insured for the type of liability that could arise under this Agreement.

15.3 No Limitation. The liability of either Party will not be limited to that which is recoverable by insurance.

ARTICLE 16

RECALL OF PRODUCT

16.1 Dynavax will be responsible for coordinating any recall of Product pursuant to the Quality Agreement. Baxter shall cooperate with Dynavax in connection with any recall, at Dynavax's expense. Dynavax will be responsible for all of the costs and expenses of all Product recalls (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom Dynavax deems appropriate).

ARTICLE 17

INTELLECTUAL PROPERTY

17.1 Existing Intellectual Property. Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other Party. Without limiting the generality of the preceding sentence, Dynavax shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all Products, BDS, Labeling and trademarks associated therewith (collectively, the “*Dynavax’s Intellectual Property*”). Neither Baxter nor any third party shall acquire any right, title or interest in Dynavax’s Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

17.2 Individually Owned Inventions. Except as the Parties may otherwise agree in writing, all Inventions (as defined herein) which are conceived, reduced to practice, or created by a Party in the course of performing its obligations under this Agreement shall be solely owned and subject to use and exploitation by the inventing Party without a duty to account to the other Party. For purposes of this Agreement, “*Invention*” shall mean information relating to any innovation, improvement development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

17.3 Jointly Owned Inventions. All Inventions which are conceived, reduced to practice, or created jointly by the Parties and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming such inventions) in the course of the performance of this Agreement shall be owned jointly by the Parties. Each Party shall have full rights to exploit such Inventions for its own commercial purposes without any obligation to the other. The Parties shall share equally in the cost of mutually agreed patent filings with respect to all such jointly owned Inventions. The decision to file for patent coverage on jointly owned Inventions shall be mutually agreed upon, and the Parties shall select a mutually acceptable patent counsel to file and prosecute patent applications based on such joint Inventions.

17.4 Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Inventions or other intellectual property, (ii) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (iii) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project.

17.5 Rights in Intellectual Property. The Party owning any intellectual property shall have the worldwide right to control the drafting, filing, prosecution and maintenance of patents covering the Inventions relating to such intellectual property, including decisions about the countries in which to file patent applications. Patent costs associated with the patent activities described in this Section shall be borne by the sole owner. Each Party will cooperate with the other Party in the filing and prosecution of patent applications. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits

for the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications.

17.6 Confidentiality of Intellectual Property. Intellectual property shall be deemed to be the Confidential Information of the Party owning such intellectual property. The protection of each Party's Confidential Information is described in Article 18. Any disclosure of information by one Party to the other under the provisions of this Article 17 shall be treated as the disclosing Party's Confidential Information under this Agreement. It shall be the responsibility of the Party preparing a patent application to obtain the written permission of the other Party to use or disclose the other Party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

ARTICLE 18

CONFIDENTIAL INFORMATION, NONDISCLOSURE AND PUBLICITY

18.1 Confidentiality. It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other. Each Party agrees to take all reasonable steps to prevent disclosure of Confidential Information to third parties. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or to obtain patents with respect to the Product.

18.2 Prior Confidentiality Agreement. This Agreement, by reference, incorporates the Confidentiality Agreement signed by Dynavax and Baxter on February 8, 2012 (the "**Confidentiality Agreement**"), and is made a part hereof as though fully set forth herein and all terms and conditions set forth in the Confidentiality Agreement shall continue to govern any disclosure made under the Confidentiality Agreement and shall govern any disclosure made as of the Effective Date of this Agreement. "**Confidential Information**", as used in this Agreement, shall have the meaning defined in the Confidentiality Agreement.

18.3 Third Party Disclosure. Baxter shall be permitted to disclose Product information to third party developmental and analytical services providers in connection with performance of its obligations hereunder provided such providers shall be subject to confidentiality agreements. Either Party may disclose Confidential Information of the disclosing Party to those Affiliates, agents, contractors and consultants who need to know such information to accomplish the purposes of this Agreement (collectively, the "**Permitted Recipients**"); provided that such Permitted Recipients are bound to maintain such Confidential Information in confidence.

18.4 Litigation and Governmental Disclosure. Each Party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for complying with applicable governmental regulations, provided that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other Party of such disclosure requirement and will use good faith efforts to assist such other Party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

18.5 Limitation of Disclosure. The Parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations

promulgated by the United States Securities and Exchange Commission (the “SEC”), and except as may be authorized in Section 18.4 and unless otherwise agreed in this Agreement, no information concerning this Agreement and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other.

18.6 Publicity and SEC Filings. The Parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the Parties. The failure of a Party to return a draft of a press release with its proposed amendments or modifications to such press release to the other Party within five (5) business days of the Party’s receipt of such press release shall be deemed as approval of such press release as received by it. Unless the prior written consent of the other Party is obtained, no Party shall, except as may be required by law or regulations (including without limitation any United States Securities and Exchange Commission filings required) in any manner disclose or advertise or publish or release for publication any statement mentioning the other Party or information contained in or acquired pursuant to this Agreement, or the fact that any Party has furnished or contracted to furnish the other Party the items required by this Agreement, or quote the opinion of any employee of the other Party. In the event Dynavax is required by law or regulation to disclose such information, each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including providing written notice to Baxter and sufficient time to review and request confidential treatment of Confidential Information of either Party included in any such disclosure. Baxter may communicate information to its investors to the extent made public by Dynavax.

18.7 Duration of Confidentiality. All obligations of confidentiality and non-use imposed upon the Parties under this Agreement, including without limitation the period of confidentiality and non-use as set forth in the Confidentiality Agreement which is hereby amended by this Section 18.7, shall expire ten (10) years after the expiration or earlier termination of this Agreement.

18.8 Production of similar products for other Clients. It is understood that Baxter may have present or future initiatives, including initiatives with third parties, involving products or processes that compete or are similar / identical with the Product Produced under this Agreement. Accordingly, Dynavax acknowledges that nothing in this Agreement shall be construed as a representation or inference by either Party that it will not develop for itself, or produce for others products or implement processes that compete with the Product or are similar / identical, provided that Confidential Information is not used in breach of this Agreement.

18.9 Reference List. Baxter shall be entitled to put Dynavax’s name on a reference list if Dynavax does not explicitly object to such procedure.

ARTICLE 19

FORCE MAJEURE

19.1 Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money) caused by an event outside the affected Party’s reasonable control shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include without limitation, acts of God; acts of public enemies; insurrections; riots; terrorist actions; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages of material, components or energy; delays in the delivery of materials, Components or energy;

23.

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acts or orders of any government or agency thereof or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause and a good faith estimate of the continuing effect of the force majeure condition and duration of the affected Party's nonperformance, and shall take whatever reasonable steps are appropriate to relieve the effect of such causes as rapidly as possible. If the period of nonperformance by Baxter because of Baxter force majeure conditions exceeds ninety (90) calendar days, Dynavax may terminate this Agreement by written notice to Baxter. If the period of nonperformance by Dynavax because of Dynavax force majeure conditions exceeds ninety (90) calendar days, Baxter may terminate this Agreement by written notice to Dynavax.

ARTICLE 20

NOTICES

20.1 All notices hereunder shall be delivered by facsimile or electronic mail, confirmed by overnight delivery with a reputable overnight delivery service, to the following address of the respective Parties:

If to Baxter: **BAXTER PHARMACEUTICAL SOLUTIONS LLC**
927 South Curry Pike
Bloomington, Indiana 47403
Attn: Contract Management

Telefax No. (812) 332-3079
Telephone No. (812) 333-0887

With a copy to: **BAXTER HEALTHCARE CORPORATION**
One Baxter Parkway
Deerfield, Illinois 60015-4633
Attn: General Counsel

Telefax No. (224) 948-2450
Telephone No. (224) 948-3440

If to Dynavax: **DYNAVAX TECHNOLOGIES**
2929 Seventh Street, Suite 100
Berkeley, California 94710
Attn: General Counsel

Email mostrach@dynavax.com
Telefax No. (510) 848-1327
Telephone No. (510) 848-5100

Notices shall be effective on the day following the date of transmission by facsimile or electronic mail. A Party may change its contact details listed above by notice to the other Party given in accordance with this Section.

24.

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

ARTICLE 21

APPLICABLE LAW

21.1 In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of Delaware, without regard to the principles of conflicts of laws. The courts of the State of Delaware shall have personal jurisdiction over the Parties hereto in all matters arising hereunder.

ARTICLE 22

ASSIGNMENT

22.1 Neither Party shall assign this Agreement or any part hereof or any interest herein to any third party (or use any subcontractor) without the prior written approval of the other Party. No consent shall be required in the case of an assignment to a Party's Affiliate or in case of a transfer to a wholly-owned subsidiary or transaction involving the merger, consolidation, or sale of all or substantially all of the assets of the Party seeking such assignment or transfer and such transaction relates to the business covered by this Agreement and the resulting entity assumes all of the obligations under this Agreement. No assignment shall be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of its obligations hereunder.

ARTICLE 23

ALLIANCES

23.1 Notwithstanding anything to the contrary herein, Baxter agrees that Dynavax shall have the right to enter into alliances with third parties who may engage in joint (with Dynavax) or unilateral marketing and promoting of the Product or any combination of products that includes the Product.

ARTICLE 24

TAXES

24.1 Dynavax shall pay all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Product to Dynavax pursuant to this Agreement or the sale or distribution of Product by Dynavax (or at Dynavax's sole expense, defend against the imposition of such taxes and expenses). Baxter shall notify Dynavax of any such taxes that any governmental authority is seeking to collect from Baxter, and Dynavax may assume the defense thereof in Baxter's name, if necessary, and Baxter agrees to fully cooperate in such defense to the extent of the capacity of Baxter, at Dynavax's expense. Baxter shall pay all national, state, municipal or other taxes on the income resulting from sale of Baxter of the services provided to Dynavax under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

25.

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

ARTICLE 25

SUCCESSORS AND ASSIGNS

25.1 This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto, their successors and permitted assigns.

ARTICLE 26

ENTIRE AGREEMENT

26.1 This Agreement and all addendums and attachments hereto (including, inter alia, the Quality Agreement), together with the Confidentiality Agreement of February 8, 2012 collectively constitutes the entire agreement between the Parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto.

ARTICLE 27

SEVERABILITY

27.1 If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

ARTICLE 28

WAIVER AND MODIFICATION OF AGREEMENT

28.1 No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties hereto. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

ARTICLE 29

INDEPENDENT CONTRACTOR

29.1 Both Parties shall act as an independent contractor for the other Party in providing the services required hereunder and shall not be considered an agent of, or joint venturer with, the other Party.

ARTICLE 30

COUNTERPARTS

30.1 For convenience, this Agreement may be executed in counterparts with the same force and effect as if each of the signatories had executed the same Agreement.

26.

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

IN WITNESS WHEREOF, the Parties have caused this Commercial Supply Agreement to be signed by their duly authorized representatives as of the Effective Date written above.

“BAXTER”

BAXTER PHARMACEUTICAL SOLUTIONS LLC

By: /s/ Robert Felicelli

Name: Robert Felicelli

Title: Global Franchise Head

“DYNAVAX”

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ Eddie Gray

Name: Eddie Gray

Title: CEO

27.

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

PRODUCT ADDENDUM

FOR

HEPLISAV™ HEPATITIS B VACCINE

THIS PRODUCT ADDENDUM is an addendum to that certain Commercial Supply Agreement of November 22, 2013 by and between **BAXTER PHARMACEUTICAL SOLUTIONS LLC** ("**Baxter**"), a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403, and **DYNAVAX TECHNOLOGIES CORPORATION** ("**Dynavax**"), a Delaware corporation having a principal place of business at 2929 Seventh Street, Suite 100, Berkeley, California 94710 (the "**Commercial Supply Agreement**").

This Product Addendum may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. Upon its execution, this Product Addendum shall become effective and shall be incorporated by reference into the previously executed Commercial Supply Agreement.

"BAXTER"

"DYNAVAX"

BAXTER PHARMACEUTICAL SOLUTIONS LLC

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ Robert Felicelli

By: /s/ Eddie Gray

Name: Robert Felicelli

Name: Eddie Gray

Title: Global Franchise Head

Title: CEO

EXHIBIT A
TO PRODUCT ADDENDUM FOR HEPLISAV™ HEPATITIS B VACCINE
PRODUCT AND PRESENTATION

Product	Presentation
HEPLISAV™ HEPATITIS B VACCINE	[*] standard syringe, with secondary package

EXHIBIT A
TO PRODUCT ADDENDUM FOR HEPLISAV™ HEPATITIS B VACCINE
ANNUAL OBLIGATION

Dynavax's Annual Obligation each year shall be the Contract Requirements of Product. During each calendar year of this Agreement, Dynavax shall purchase the Contract Requirements and meets its Annual Obligation as specified in Article 4.

30.

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

EXHIBIT B
TO PRODUCT ADDENDUM FOR HEPLISAV™ HEPATITIS B VACCINE
ANNUAL ORDER MAXIMUM

In any calendar year during the Term of this Agreement, in no event shall Baxter be obligated to Produce more than a total maximum of [*] Units of Product; provided, however, Baxter will use good faith efforts to meet such increased demand.

31.

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

EXHIBIT C
TO PRODUCT ADDENDUM FOR HEPLISAV™ HEPATITIS B VACCINE
PRICING

Batch	Price*
GMP Stability Batch (~[*] Units or ~[*])	[*] per Batch
Process Validation Batch (~[*] Units or ~[*])	[*] per Batch
Process Validation Batch (~[*] Units or ~[*])	[*] per Batch

Volume**	Manufacturing Price + Finishing Price***
Up to [*] Units per year	[*] per Unit
[*] to [*] Units per year	[*] per Unit
[*] to [*] Units per year	[*] per Unit
[*] to [*] Units per year	[*] per Unit

* The Batch pricing does not include the cost for finishing and does not include the cost of the primary packaging Components (syringes, stoppers and plunger rods) which will be invoiced by Baxter separately.

** For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is “trued up” at the end of each calendar year (i.e. the first [*] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Baxter at [*] per Unit (as adjusted) and the second [*] will be charged at [*] per Unit (as adjusted) and so on even if Dynavax purchases over [*] Units of commercial Product in a calendar year).

*** The cost of the primary packaging Components (syringes, stoppers and plunger rods) is not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Baxter separately.

Note: All pricing assumes automated inspection. In the event manual inspection is required, the pricing referenced above may change. The Unit pricing shown in the table above assumes that the secondary packaging materials used for Product will include cartons, [*] blisterpacks with tyvek lids, unit labels and back stops. Such Unit pricing is subject to change based on the final selection of secondary packaging materials to be used for Product.

EXHIBIT D
TO PRODUCT ADDENDUM FOR HEPLISAV HEPATITIS B VACCINE
INITIAL LONG RANGE FORECAST

Year	Forecast
2013	Units
2014	Units
2015	Units
2016	Units
2017	Units
2018	Units

Within thirty (30) days from the Effective date of this Agreement, the Parties agree to amend this Exhibit D to incorporate the Initial Long Range Forecast (the "**First Amendment**"). Upon the effective date of the First Amendment, this Exhibit D shall be amended to incorporate the Initial Long Range Forecast as though fully set forth herein.

33.

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

SUPPLY AGREEMENT

THIS AGREEMENT is entered into as of November 2, 2016, (the “*Effective Date*”) by and between DYNAVAX TECHNOLOGIES CORPORATION, a company established pursuant to the laws of Delaware, with its registered office at 2929 Seventh Street, Suite 100, Berkeley, California 94710, hereinafter referred to as “*Buyer*,” and BECTON, DICKINSON AND COMPANY, a corporation organized under the laws of New Jersey, with a place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417-1866 hereinafter referred to as “*BD*.” Buyer and BD are also referred to collectively herein as the “*Parties*” and each a “*Party*.”

WHEREAS, Buyer is engaged in the development of compounds which can be delivered with the drug delivery devices and/or containers and/or delivery systems manufactured by BD; and

WHEREAS, BD desires to manufacture and supply to Buyer certain drug delivery devices and/or drug container and/or delivery systems; and

WHEREAS, Buyer desires to purchase such devices and/or containers and/or delivery systems from BD in accordance with the terms and conditions set forth herein in order to use them as delivery devices for use with the Compound (as hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, the Parties hereto agree to the following terms and conditions:

1. DEFINITIONS.

Each of the capitalized terms used in this Agreement (other than the headings of the paragraphs), whether used in the singular or the plural, shall have the meaning as set forth below or if not listed below, the meaning designated elsewhere in this Agreement.

1.1 “*Affiliate*” shall mean (a) any entity that is a subsidiary (as hereinafter defined) of a Party, (b) any entity of which a Party is a subsidiary, and (c) any entity that is a subsidiary of another entity of which a Party is a subsidiary. For purposes of this definition, “*subsidiary*” means an entity in which another entity holds directly or indirectly at least fifty percent (50%) of the voting stock.

1.2 “*Agreement*” shall mean the agreement set out herein together with the Schedules hereto.

1.3 “*Compound*” shall mean Buyer’s compounds identified on Schedule 2, which may be updated from time to time following both Parties’ agreement.

1.4 “*End Product*” shall mean the Product filled by Buyer with the Compound.

1.5 “*Product*” shall mean the BD device(s), container(s), system(s) and/or component(s) listed on Schedule 3.

1.6 “*Specifications*” shall mean the BD Medical — Pharmaceutical Systems Quality Specifications set forth on Schedule 3 for the applicable Product and may be modified or supplemented from time to time as contemplated herein.

2. SCOPE & OTHER AGREEMENTS

BD shall manufacture and supply to Buyer Product solely for use by Buyer with the Compound in the End Product. The BD Medical Pharmaceutical Systems – United States Standard Terms and Conditions of sale are hereby included as Schedule I to this Agreement (the “**BDM PS Standard Terms and Conditions of sale**”). The terms of this Agreement, including the BDM PS Standard Terms and Conditions of sale, shall govern the sale of Products hereunder. In case of discrepancies between the terms in the body of this Agreement and those of BDM PS Standard Terms and Conditions of sale, the terms within the body of this Agreement shall prevail. Notwithstanding Section 13.4, or any provision to the contrary contained herein, the CDA (as hereinafter defined) shall remain in full force and effect in accordance with its terms. In the event that the Parties have signed or subsequently sign a quality agreement for the Products, (the “**Quality Agreement**”), it shall automatically be incorporated into this Agreement as an attachment. In case of discrepancies between the terms of such Quality Agreement and the terms of this Agreement, the terms of the Quality Agreement shall prevail for quality related matters and the terms of this Agreement shall prevail for other matters. Notwithstanding anything to the contrary, (i) all orders of Products may be submitted to BD by Baxter Pharmaceutical Solutions LLC or its affiliates (collectively, “**Baxter**”) on behalf of Buyer, and may be delivered to a Baxter location if so specified in the applicable purchase order, and (ii) all Products may be supplied to, inspected by and used by Baxter on behalf of Buyer under this Agreement.

3. DURATION.

The manufacture, purchase and sale obligations of this Agreement shall be deemed to commence on the Effective Date and shall remain in effect for a period of three (3) years from the Effective Date unless terminated earlier in accordance with the provisions of this Agreement. Thereafter, this Agreement shall automatically renew for a maximum of two successive one (1)-year terms unless either Party gives written notice to the other Party of its intent not to renew no later than [*] prior to the expiration of the then-current term.

4. SALE & PURCHASE.

4.1 FORECASTS. Buyer shall use its best efforts to assist BD with its production planning by providing BD by the Effective Date with a written forecast of Buyer’s best estimates of its Product requirements, stated on a monthly basis as multiples of BD’s standard minimum lot sizes, for the twelve (12)-month period beginning on the Effective Date. Thereafter, each month Buyer shall, no later than the 2nd Wednesday of every month, provide BD with a monthly Product forecast for the twelve (12)-month period beginning on such date. In addition, Buyer shall provide to BD every year in December a plan with its good-faith volume estimations for the following three (3) years.

4.2 Prices for the Product shall be as set out in Schedule 3 hereof from the Effective Date until one (1) year thereafter. In the event of a raw material price increase, the Parties shall meet to discuss in good faith any required price change. In addition, BD may increase prices in the event (i) the cost of manufacturing and supplying the Product (including the costs of raw materials included therein) has increased, (ii) changes are made to the Specifications of the Product, or (iii) other regulatory or legislative changes or other unforeseen economic, legal or competitive factors affecting BD. Price increases will occur no more than once per year and will not exceed a maximum of [*]. If the Parties are unable to agree on price changes as per this Section 4.2 within 60 days after BD first gives notice of a requested price change, each Party is entitled to terminate this Agreement with [*] written notice to the other. All purchase orders shall specify the applicable prices for Product then in effect pursuant to this Agreement.

2.

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4.3 BD shall invoice Buyer for each shipment of Product with payment due net [*] of date of invoice. Buyer shall submit written purchase orders to BD, stated as multiples of BD's standard minimum lot size for the Product ordered, within the lead times set forth in Schedule 3 prior to the requested date of delivery.

4.4 All purchase orders are subject to BD's acceptance. BD shall within [*] confirm in writing receipt and acceptance of purchase orders submitted to it, including the currently planned delivery date. Orders accepted by BD in writing are binding and not subject to modification without the written agreement of both Parties.

5. DELIVERY, RISK AND TITLE.

5.1 The Product shall be packed and shipped in accordance with the Specifications. BD shall deliver Product to Buyer EXW (Incoterms 2010) BD facility. Title to Product shipped by BD for a given Purchase Order and risk of loss or damage shall pass to Buyer upon delivery to the common carrier. Buyer shall specify in the applicable purchase order the destination for each shipment. The quantity shipped may vary within $\pm 10\%$ of the confirmed order. No provision on BD's invoice or Buyer's purchase order forms (including any Purchase Orders accepted hereunder) which may purport to impose different or additional conditions than those provided herein shall be of any force or effect. All Documentation required in connection with a shipment shall be forwarded to the attention of the following:

Dynavax Technologies Corporation
2929 Seventh Street, Suite 100
Berkeley, CA 94710
Attn: Sr. Director, Supply Chain Management
Telecopier Number - (510) 848-1327

6. REGULATORY SUPPORT

6.1 BD shall provide to Buyer documentation related to the Product to support the marketing approval of Buyer's End Product (the "**Standard Regulatory Package**").

6.2 The Standard Regulatory Package shall include:

(i) If the Product is a registered Medical Device owned by BD: The proof of registration of the Medical Device (includes but not limited to: registration certificate, Declaration of Conformity, etc.)

(ii) If the Product is a component of the End Product Container Closure System:

- A Technical Dossier of the Product, to be requested by Buyer through the BD Portal: www.bd.com/pharmaceuticals/regulatory.
- For Submission in countries where Health Authorities accept this document, a Letter of Authorization making reference to the Master File of the Product, to be requested by Buyer through the BD Portal: www.bd.com/pharmaceuticals/regulatory.

3.

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6.3 The Parties agree that should Buyer need a regulatory support that is not part of the Standard Regulatory Package nor a statement related to the claim made by BD in the Technical Dossier, the Parties shall negotiate in good faith the type of information and/or documentation to be provided by BD as well as the appropriate timelines and payment to BD for such deliverables.

6.4 Buyer shall have the sole responsibility for obtaining and maintaining all governmental or regulatory licences, authorizations, registrations and clearances for use and sale of any End Product.

7. QUALITY, INSPECTION, ACCEPTANCE OR REJECTION OF PRODUCT.

7.1 BD will, upon reasonable prior notice, permit duly authorized representatives of Buyer to visit and inspect the process of manufacture by BD of the Product, provided, that such visits and inspections shall be subject to appropriate customary BD policies, restrictions and confidentiality obligations set forth in Section 8.

7.2 BD intends to promote continuous quality improvements relating to the Product and its manufacturing processes. BD is entitled to make materials and process changes to the Specifications that do not affect or that improve the quality of the Product and its suitability for the purposes of the Buyer. BD shall provide Buyer with notice of any changes to the Product in accordance with BD's Customer Notification of Change procedure in alignment with the Quality Agreement.

7.3 Promptly upon receipt of each shipment of Product, Buyer will perform thorough incoming inspection in accordance with best-practice pharmaceutical industry standards. In addition to incoming inspection, and before any use of the Product, Buyer shall thoroughly and with reasonable care inspect the Product for conformity to Specifications. If at any time Buyer finds that the Product did not conform to the Specifications at the time of delivery, Buyer shall immediately and in any event no later than forty-five (45) days after the delivery of the Product, give BD written notice of any claim setting forth the details of such non-conformity; in the absence of such notice, Buyer shall be deemed to have accepted the Product. Buyer shall comply with BD's reasonable requests concerning complaint handling, including, without limitation, providing samples of the purportedly non-conforming Product or, if this is not possible, providing detailed photographs thereof. BD shall, if it accepts such notice of claim, replace any non-conforming Product or parts thereof at BD's expense and at no cost to Buyer or, if replacement of the Product is not possible for any reason, issue a credit note to Buyer for an amount equal to the purchase price of the non-conforming Product, provided that such non-conformity existed at the time of delivery. Any Product that does not conform to the Specifications at the time of delivery shall, at BD's request, either be returned to BD or destroyed at BD's expense. Payment for Product prior to acceptance shall not constitute automatic acceptance by Buyer. Acceptance of out-of-specification Product with undetected, latent defects shall not relieve BD from its warranty of conformity under this Agreement, including the BDM PS Standard Terms and Conditions of Sale in Schedule 1, for such latent defects or as otherwise provided herein. Latent defects that were not reasonably discoverable at the time of delivery must be promptly notified to BD by Buyer after Buyer discovers the existence of any such latent defect in a Product, and in any event no later than [*] thereafter, failing which Buyer will be deemed to have accepted such latent defect. BD's sole obligation under the warranties set forth in this Agreement, including the BDM PS Standard Terms and Conditions of Sale in Schedule 1, and Buyer's sole and exclusive remedy, shall be the replacement of, or credit for, any defective or non-conforming Product as provided in this Section 7.3. except to the extent there is a Claim (as defined below) under Section 8.9.

7.4 Buyer assumes entire responsibility for (i) evaluating the safety, efficacy and appropriateness of the Products for Buyer's intended use in the End Product and any other use, including

4.

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any such use with Buyer's or any third party's compounds or other materials, (ii) validating the Product with respect to all materials, processes, storage, handling, and other uses and treatments thereof and (iii) its assembly, filling, labeling, packaging, storing and use of the Product, the End Product and any other product incorporating or including the Product, all in accordance with recognized Good Manufacturing Practices and other appropriate, recognized industry standards. Furthermore, Buyer acknowledges that many jurisdictions have in effect laws, rules and/or regulations ("**Safety Laws**") mandating or recommending the use of protection technologies in connection with drug delivery devices and containers ("**Safety Products**"). Buyer has been and will be solely responsible for making its own analysis of such Safety Laws and Safety Products as well as traditional devices, containers and components in choosing the components used in the End Products.

7.5 BD shall promptly acknowledge and accept any valid warranty claim and provide Buyer with replacement Product or parts thereof or, if replacement of the Product is not possible for any reason, issue a credit note to Buyer for an amount equal to the purchase price of the non-conforming Product to the extent necessary to meet BD's warranty obligations under this Agreement, including under the BDM PS Standard Terms and Conditions of Sale in Schedule 1 or make good any shortages or non-completed deliveries. If BD does not accept a claim it will promptly inform Buyer in writing of its reasons. In the event the Parties disagree as to whether the Product conforms to the Specifications, the rejected Product shall be submitted to a mutually acceptable third party testing laboratory, which will determine whether such Product meet the Specifications. The Party against whom the testing laboratory rules will bear the reasonable costs of the testing laboratory. If the testing laboratory rules that the Product meets the Specification, Buyer will purchase the Product at the agreed-upon price, irrespective of whether BD has already replaced such Product. If the testing laboratory rules that the Product does not meet the Specifications and the Product was not previously replaced, BD shall issue a credit note to Buyer for an amount equal to the purchase price of the rejected Product

8. PRODUCT WARRANTIES; REPRESENTATIONS, WARRANTIES AND COVENANTS; INDEMNIFICATION.

BD represents, warrants and covenants to Buyer as follows:

8.1 Each Product shall conform to and will be produced in accordance with the Specifications, the warranties set forth in this Agreement and all applicable federal, state and local laws. The Product warranties under this Agreement shall be void to the extent that Buyer has misused, neglected, improperly handled, altered, abused or used the Products for any purpose other than the one for which they were manufactured, or if the Products' failure to conform to the foregoing warranty was due in whole or in part to other conditions beyond the control of BD. THE WARRANTIES SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED BY STATUTES OR OTHERWISE ARE HEREBY DISCLAIMED. Except for a claim for which BD is obligated to indemnify Buyer hereunder, BD's liability to Buyer with respect to a non-conforming Product shall be limited to the repair or replacement of such non-conforming Product or the return of the purchase price for such Product at BD's discretion.

8.2 BD has, will maintain and will comply with, all permits, licenses and other authorizations that are required under all federal, state and local laws, rules and regulations applicable to BD's obligations under this Agreement.

5.

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

8.3 BD hereby represents warrants and covenants, subject to the provisions set forth below, as follows:

(i) neither it nor, any individual employed or engaged by it is currently or has ever been (a) debarred pursuant to the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335(a)), as amended, or any similar state law or regulation or convicted of a felony for conduct relating to the regulation or handling of drug product; (b) excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, et seq. or any state agency from participating in any United States federal or state health care program; or (c) otherwise disqualified or restricted by the United States Food and Drug Administration pursuant to 21 C.F.R. 312.70 or any other regulatory authority; and

(ii) BD will notify Buyer immediately in the event that it, or any individual employed or engaged by it, comes under investigation for debarment, exclusion or disqualification or is debarred, excluded or disqualified in any manner contemplated in the above paragraph (1).

8.4 The Products and BD's manufacture of Products in the performance of this Agreement will not, to the best of BD's knowledge, infringe upon the intellectual property or other rights of any third party.

8.5 BD shall comply with the terms and conditions of any applicable quality agreement between BD and Buyer in effect from time to time.

8.6 In the event of a voluntary or mandatory recall, warning, field correction or withdrawal of a Product, BD shall give Buyer prompt written notice thereof (which shall be in no event be later than forty-eight (48) hours after initiating such recall). In the event of a voluntary or mandatory recall, warning, field correction or withdrawal of an End Product, Buyer shall give BD prompt written notice thereof (which shall be in no event be later than forty-eight (48) hours after initiating such recall). In such cases, the Parties shall discuss in good faith the consequences in accordance with the terms of this Agreement.

8.7 BD shall indemnify, defend and hold harmless Buyer and its affiliates, officers, directors, employees, consultants, agents and representatives (collectively, the "**Buyer Indemnitees**") from all third party claims, demands, actions, causes of action, losses, judgments, damages, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees and court costs) related thereto (each, a "**Claim**") to the extent such Claim arises out of or relates to death or bodily injury caused by the use of a Product that does not conform to the warranties set forth in this Agreement.

8.8 Buyer shall indemnify, defend and hold harmless BD and its affiliates, officers, directors, employees, consultants, agents and representatives (collectively, the "**BD Indemnitees**") from all Claims to the extent such Claim arises out of or relates to the use or sale of the Products by Buyer, except to the extent that such Claim arises out of the failure of such Products to meet the warranties set forth herein.

9. CONFIDENTIALITY.

9.1 Confidentiality provisions shall be as set forth in the terms and conditions agreed upon in the current Confidential Disclosure Agreement dated February 16, 2012, as amended from time to time (the "**CDA**").

6.

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

9.2 Notwithstanding the foregoing, or any other provision herein to the contrary, in connection with Buyer's registration of the End Product with any regulatory body or governmental authority, Buyer may disclose Confidential Information in whole or in part to: (i) Buyer's Affiliates conducting the End Product registration, (ii) such regulatory body or governmental authority when such disclosure is required in connection with the registration of the End Product with such regulatory agency or governmental authority, but solely to the extent and in the amount required by such regulatory agency or authority to enable Buyer to obtain registration, and (iii) third parties which are involved in the registration process, but solely to the extent and in the amount required for such third party to perform its part of the registration process, provided in each case set forth above that, to the extent possible, Buyer shall request confidential treatment for all data so disclosed and the recipient(s) of such data shall not remove, alter or obscure any confidentiality markings .

10. EARLY TERMINATION. This Agreement may be terminated prior to the end of its term as follows:

10.1 By either Party if the other Party fails to perform or otherwise breaches any of its material obligations hereunder, by giving notice of its intent to terminate and stating the grounds therefore. The Party receiving such notice shall have sixty (60) days from the receipt thereof, to cure the failure or breach, at the expiration of which this Agreement shall terminate if such failure or breach has not been cured. If, within such sixty (60) day period after receipt of such notice, the defaulting Party remedies the condition forming the basis for the termination, such notice shall cease to be operational and the Agreement shall continue in full force and effect.

10.2 BD shall have the right to terminate this Agreement upon thirty (30) days written notice to Buyer if BD is required to cease manufacturing the Product for more than sixty (60) days due to quality or other restrictions requested or imposed by any regulatory or other governmental authority.

10.3 Expiration or termination of this Agreement, for whatsoever reason, shall not affect any rights or obligations of either Party that have already accrued or are intended by the Parties to survive such expiration or termination. Notwithstanding the foregoing, no such expiration or termination, other than a termination by Buyer pursuant to Section 10.1 above, shall relieve Buyer of its obligation to purchase Product for which purchase orders have been accepted by BD.

11. ASSIGNMENT.

11.1 Neither Party may assign or delegate this Agreement, in whole or in part, or any interest arising under this Agreement to any third party other than to an Affiliate of such Party or to a purchaser of all or substantially all of such Party's assets and business, without the prior written consent of the other Party, which consent shall not be unreasonably withheld. No such assignment or delegation shall be deemed or operate to relieve the assigning or delegating Party from any liabilities or obligations assumed or to be performed by it hereunder. Subject to the provisions of this Section 10, this Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of the Parties hereto.

11.2 Notwithstanding the foregoing, BD may not use subcontractors to manufacture some or all of the Products, but may use subcontractors to provide raw materials or sub-parts of Products or equipment required for BD's manufacture of the Product and BD shall be responsible to Buyer for the acts of such subcontractors as if such acts had been performed by BD.

7.

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

12. NOTICE.

12.1 Any notice required hereunder may be served by either Party on the other by personal delivery, facsimile (upon confirmation of receipt), or by sending same post-prepaid, by registered or certified mail or reputable overnight courier service to the respective Party's address set forth below:

BD:

Becton, Dickinson and Company
Becton Drive
Franklin Lakes, New Jersey 07417-1880
Attention: Vice President and General Manager
BD Medical, Pharmaceutical Systems
Fax No. (201) 847-4847

Buyer:

Dynavax Technologies Corporation
2929 Seventh Street, Suite 100
Berkeley, California 94710
Attention: Senior VP, Operations and Quality
Fax No.: (510) 848-1327

With a copy to:

Dynavax. Technologies Corporation
2929 Seventh Street, Suite 100
Berkeley, California 94710
Attention: General Counsel
Fax No.: (510) 848-1327

, or to such other address as a Party may notify the other as provided herein. Notice shall be deemed given upon actual receipt or refusal to accept same.

13. INDEPENDENT CONTRACTOR/SUB-CONTRACTORS.

Each Party agrees to perform under this Agreement solely as an independent contractor and shall not hold itself out as an employee, agent or representative of the other in any manner whatsoever.

14. MISCELLANEOUS.

14.1 The failure of either Party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights.

14.2 Each Party warrants that it has all the necessary rights and powers to grant the rights to the other Party as provided in this Agreement, and that the execution, delivery and performance of this Agreement does not and will not result in a violation or conflict with any agreements with third parties.

14.3 This Agreement, together with any Schedules attached hereto, constitutes the complete and entire understanding between the Parties with respect to the subject matter hereof. In the event of any ambiguity or contradiction between the body of this Agreement and the Schedules, the body of this Agreement shall rank before the Schedules. No provision on Buyer's purchase order forms or other Buyer commercial or contractual documents, such as general conditions of purchase, or on BD's other commercial or contractual documentation not included herein, which may purport to impose different or additional conditions upon a Party than those provided for herein, shall have any force or effect.

14.4 This Agreement supersedes all prior agreements, arrangements and undertakings relating to the subject matter hereof between the Parties. No changes or modifications are to be made to this Agreement unless evidenced in writing and signed for and on behalf of both Parties.

14.5 If any provision of this Agreement is deemed or held to be illegal, invalid, unenforceable or contrary to any laws or regulations, all other provisions will continue in full force and effect, and the Parties where possible will substitute for such provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties or such provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

14.6 Buyer shall not use any promotional material that makes reference to the Product without the prior written consent of BD.

14.7 The Section headings used in this Agreement are provided as a matter of convenience and shall not affect the construction or interpretation of any of its provisions.

14.8 This Agreement and all disputes arising hereunder will be governed by and interpreted in accordance with the internal laws of the State of Delaware without giving effect to the principles of conflicts of laws. The parties agree that the venue for resolving all disputes under this Agreement shall be in the courts of the State of Delaware.

14.9 Except for a Claim for which a party is entitled to be indemnified under this Agreement or for a breach of Section 9 (Confidentiality), neither Party shall be liable hereunder for any special, indirect, consequential or incidental damages, including, but not limited to, loss of actual or anticipated profits or revenues, loss by reason of shutdown, loss of use, non-operation or increased expense of manufacturing or operating, or damage to or loss of other products, property and/or equipment, or loss of reputation or opportunities.

14.10 Neither party shall be liable for any damages that result from a force majeure event, which shall include acts of God, acts of the public enemy, war, terrorism, insurrections, riots, injunctions, embargoes, fires, explosions, floods or other unforeseeable causes beyond the reasonable control, and without the fault or negligence, of the affected party. The affected party shall promptly notify the other party of such event and shall resume performing its affected obligations under this Agreement as soon as practical after such event.

IN WITNESS WHEREOF, the Parties hereto have on the dates entered below executed this Agreement in two originals, of which the Parties shall keep one each.

BECTON, DICKINSON AND COMPANY

DYNAVAX TECHNOLOGIES CORPORATION

/s/ Thomas Koning

By: Thomas Koning

Title: V.P. of Sales – NA, EU, Middle East & Africa

Date: 8 November 2016

Place: Franklin Lakes, NJ

/s/ David Novack

By: David Novack

Title: SVP Tech Ops and Quality

Date: 2 November 2016

Place: Berkley, CA

10.

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SCHEDULE I

BD MEDICAL PHARMACEUTICAL SYSTEMS - UNITED STATES STANDARD TERMS AND CONDITIONS OF SALE

GENERAL: These general terms and conditions of sale ("**Terms and Conditions**") exclusively will govern the sale by BD Medical, Pharmaceutical Systems US (a business unit within the BD Medical Segment of **BECTON, DICKINSON AND COMPANY**, hereinafter referred to as "**BD**") of all products and services ("**Products**" and "**Services**," as applicable) to Buyer. No addition or modification of these Terms and Conditions will be binding on BD unless agreed to in writing signed by an authorized representative of BD. BD objects to other terms and conditions that may be proposed by the Buyer. Acceptance by BD of Buyer's purchase order(s) is expressly conditioned on Buyer's assent to all of the Terms and Conditions contained herein.

CUSTOMER TESTING AND VALIDATION: Buyer is solely responsible for evaluating the appropriateness of the Products and Services for Buyer's intended use, including any such use with Buyer's or third party's compounds or other materials comprising part of Buyer's processes, components and products, and Buyer is further solely responsible for validating the Products with respect to all uses, materials and processes.

WARRANTY AND LIMITATION OF LIABILITY:

BD represents and warrants that at the time BD ships the Products or performs Services, such Products or Services, as the case may be, shall meet the BD specifications relating thereto and shall be free from rightful claim of third parties for infringement of patent, copyright or trade secret. The foregoing warranty shall be void if the Products have been misused, neglected, improperly handled, altered, abused or used for any purpose other than the one for which they were manufactured or if the Products' failure to conform to the foregoing warranty was due in whole or in part to other conditions beyond the control of BD. **THE WARRANTY SET FORTH IN THIS PARAGRAPH IS EXCLUSIVE REGARDING THE PRODUCTS AND IN LIEU OF ALL OTHER WARRANTIES EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED BY STATUTES OR OTHERWISE ARE HEREBY EXPRESSLY DISCLAIMED.**

BD's liability in connection with the Products and the supply thereof shall be limited to the repair or replacement of such Products or the return of the purchase price for such Products at BD's discretion. Buyer agrees that BD is not responsible for any indirect, consequential, or business damages (including without limitation, loss of profit or use), which may be suffered as a result of BD's breach of any contract, representation, or warranty or as a result of your sale or the use of the Products. Buyer further agrees that BD shall not be liable for any damages that may result from a force majeure, which shall include acts of God, acts of the public enemy, war, terrorism, Insurrections, riots, injunctions, embargoes, fires, explosions, floods, or other unforeseeable causes beyond the reasonable control, and without the fault or negligence of, BD.

INDEMNIFICATION: Buyer shall indemnify and hold harmless BD, its affiliates, directors, officers, employees and agents from and against any suits, claims, losses, demands, liabilities, damages, costs and expenses (including costs, reasonable attorney's fees and reasonable investigative costs) in connection with any suit, demand or action by any third party to the extent such suit, demand, or action arises out of or results from its use or sale of the Products purchased by buyer from BD, except to the extent that such suit, demand or action arises out of the failure of such Products to meet the warranty set forth above.

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EXPORT LAW COMPLIANCE: U.S. law regulates the export, re-export or other transfer of the Products that are sold by BD and purchased under the terms set forth herein. Any required U.S. and non-U.S. government authorization must be obtained prior to shipment, and diversion contrary to U.S. and non-U.S. law is prohibited. By ordering these Products from BD, the recipient agrees to comply fully with all applicable export control laws and regulations of the United States and applicable foreign governments, and expressly assumes responsibility for determining whether a subsequent transaction requires U.S. and non-U.S. government authorization and, if so, for obtaining such authorization before shipping or otherwise transferring the Products to another party.

Buyer shall not knowingly use, resell or distribute any BD Product directly or indirectly for the development, production or proliferation of weapons of mass destruction (nuclear, chemical or biological) or missile delivery systems, and/or for terrorist activities.

ORDERS: All orders must be in writing and include an order number, a full and accurate description of each Product ordered (e.g. sterile or non-sterile, with or without needle, rubber formulation of plunger stoppers, tip caps or needle shields, material, size and color of plunger rods, and any other relevant information), the quantity of each Product ordered, the price quoted by BD, the requested delivery date and the delivery and invoicing address for the Products ordered. BD part numbers should also be included for all Products whenever possible. BD shall not be liable for any shipment error caused by incorrect or incomplete information provided with the order. The order shall not be deemed accepted until confirmed by BD. No confirmed order may be cancelled or changed without the prior written approval of BD.

DELIVERY: BD shall deliver Products to Buyer EXW (Incoterms 2010) BD facility. Title to Products shipped by BD for a given Purchase Order and risk of loss or damage shall pass to Buyer upon delivery to the common carrier. Buyer shall specify in the applicable purchase order the destination for each shipment. The quantity shipped may vary within +/-10% of the confirmed order. No provision on Buyer's purchase order (including any Purchase Orders accepted hereunder) which may purport to impose different or additional conditions than those provided herein shall be of any force or effect.

PRICING: Unless otherwise indicated, prices or BD quotations are per thousand units. Prices prevailing at time of shipment. Prices are subject to annual changes due to fluctuations in material or component prices or other market conditions.

PAYMENT TERMS: Net 30 days from date or invoice. A monthly service charge of 1.5% will be added to all past due balances.

WAREHOUSING: Customer requests to delay shipments more than 60 days may result in inventory carrying charges of 1.5% per month.

GOVERNING LAW AND JURISDICTION: This agreement and all disputes arising hereunder and/or related to the BD Products purchased by buyer will be governed by and interpreted in accordance with internal laws or the State of New Jersey without giving effect to the principles of conflict of laws. The parties hereby consent to and agree that the United States Federal Courts for the District of New Jersey, and State Courts or New Jersey, shall have the sole and exclusive jurisdiction to resolve all such disputes. The parties hereby waive any objection to such sole and exclusive jurisdiction.

SCHEDULE 2

COMPOUND

Product:	NDC:
Heplisav	43528-003-05

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SCHEDULE 3

Product Description / Pricing

	BD Product/Description	Cat #	\$/1,000	Standard Lead Times
1	Barrel: HYPAK SCF 1mL RF PRTC W7025/65 DHB PPL	47339219	[*] per 1,000 units	[*]
2	Backstop: HYPAK BS 1-3mL PP CLEAR	47094927	[*] per 1,000 units	[*]
3	Backstop: HYPAK BS 1-3mL PP CLEAR	47094906	[*] per 1,000 units	[*]
4	Plunger Rod: HYPAK 1.5mL PP	47325919	[*] per 1,000 units	[*]

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SUPPLY AGREEMENT

THIS AGREEMENT is dated October 1, 2012 and is made by and between DYNAX TECHNOLOGIES CORP., a corporation of the State of Delaware, with an address at 2929 Seventh Street, Suite 100, Berkeley, CA 94710 (“*Customer*”) and NITTO DENKO AVECIA INC., a corporation of the State of Delaware, with an address at 125 Fortune Boulevard, Milford, Massachusetts 01757 (“*Avecia*”). Customer and Avecia are sometimes referred to herein individually as a “*Party*” and collectively as “*Parties*”.

WHEREAS, Avecia has knowledge and experience with regard to the GMP manufacture of oligonucleotides with significant expertise in process technologies, research and development and process scale-up;

WHEREAS, Customer conducts research and development in relation to certain oligonucleotides with a view to conducting clinical trials and seeking registration of the oligonucleotides in drug products for the treatment of human diseases;

WHEREAS, Customer has a vaccine product for the prevention of hepatitis B which is currently in Phase 3 clinical trials; and

WHEREAS, Customer and Avecia desire to enter into this Agreement to set forth the terms and conditions upon which Avecia will supply to Customer one of the components of the vaccine product for clinical and commercial use.

NOW, THEREFORE, intending to be legally bound, it is hereby agreed as follows:

1. DEFINITIONS.

“*Affiliate*” means any person, organization, corporation or other business entity, controlling, controlled by or under common control with Customer.

“*Agreement Year*” means any period of twelve consecutive calendar months beginning with the first full calendar month following the Effective Date.

“*Applicable Laws*” means applicable federal, state and local laws, rules, regulations and ordinances within the United States of America (the “*USA*”), including without limitation GMP.

“*Batch*” means a specific quantity of Product that is intended to be of uniform character and quality and is produced during the same cycle of manufacture as defined by the applicable batch record.

“*Confidential Information*” means any technical, business, financial and other commercial information of a confidential nature disclosed (whether disclosed in writing, orally, by way of sample or by any other means and whether directly or indirectly) by either Party (the “*Disclosing Party*”) to the other Party (the “*Receiving Party*”).

“*Current Process*” means the [*] process for manufacture of Product, as existing on the Effective Date, which has been previously validated by Avecia.

“**Effective Date**” means the date of this Agreement.

“**Exclusive Period**” means the period commencing on the Effective Date and ending on the earlier of the date that is [*] after the date of Regulatory Authority Approval, or [*] from the Effective Date.

“**Facility**” means Avecia’s GMP facility located in Milford, MA.

“**GMP**” means current good manufacturing practice and standards as provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations to the US Code of Federal Regulations, Title 21 (21 CFR 210 and 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7, and subject to any arrangement, additions or clarifications agreed from time to time between the Parties in the Quality Agreement.

“**Independent Intellectual Property**” shall have the meaning set forth in **Section 10**.

“**Intellectual Property**” means patents, patent applications, all provisional, divisional, continuations, renewals, continuations in part, reexaminations, patents of addition, supplementary protection certificates, extensions, letters of patent, registration or confirmation patents and reissues with respect to any patents described in the foregoing clauses, any know how, trade secrets, data, technology and technical information.

“**Latent Defect**” means any failure of a Product to meet Product Requirements that is not actually known to Customer and not readily discoverable by Customer using commercially reasonable inspection procedures, in each case at the time of Customer’s acceptance of such Product.

“**Licensee**” means and includes any person licensing the right to manufacture or market Product or any other drug product which contains Product from Customer or any Affiliate of Customer.

“**New Process**” means process changes to the Current Process as contemplated in **Section 2** and **Appendix 2**.

“**New Process Strategy**” means the strategy for implementing a New Process as set forth in **Appendix 2**.

“**Product**” means the compound identified as 1018 ISS (AGU), [*].

“**Product Requirements**” means conformance with (a) GMP, (b) Product Specifications, (c) the Current Process or the applicable New Process, as the case may be, and (d) the Quality Agreement.

“**Product Release Date**” means, with respect to any Product sold by Avecia to Customer hereunder, the date of sign off by the Avecia Quality Assurance Department (“**Avecia QA**”) on the executed batch records and the analytical report for all Product release testing under Avecia control or for which Avecia is expressly responsible.

“**Product Specifications**” means the specifications for the Product as agreed and modified from time to time by the Parties.

2.

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“**Quality Agreement**” means the document agreed to by the Parties in the form attached hereto as **Appendix 3**, as amended, supplemented or restated from time to time.

“**Regulatory Authority**” means the USA Food and Drug Administration (the “**FDA**”) or an instrumentality of any country outside of the USA that performs a function for such country similar to the function performed by the FDA for the USA with regard, among other things, to the approval, licensing, registration or authorization to manufacture, promote, market, distribute, use, store, import, transport or sell a product in the defined territory or political subdivisions.

“**Regulatory Authority Approval**” means the first approval commercially to manufacture, promote, market, distribute and sell the Product by a Regulatory Authority.

“**Rolling Forecast**” shall have the meaning set forth in **Section 4.2**.

2. CURRENT PROCESS; NEW PROCESS IMPLEMENTATION; OTHER PROCESS IMPROVEMENTS.

2.1 The initial pricing, campaign size and capacity availability for Product formulated for this Agreement are based upon the Current Process. In anticipation of the possibility for significant beneficial changes to the Current Process, the Parties have developed a strategy for implementing a new process (“**New Process**”), which strategy is attached hereto as **Appendix 2** (the “**New Process Strategy**”).

2.2 At any time prior to the [*], Customer may request Avecia to implement the New Process Strategy, in which case Avecia shall promptly initiate and perform the tasks set forth in the New Process Strategy using commercially reasonable and diligent efforts and in a professional and timely manner, consistent with standards then customary in the oligonucleotide industry, and, in any event, with at least the degree of care and quality that Avecia uses to perform similar activities for other parties. At Customer’s request, the Parties shall negotiate in good faith and execute a development services agreement that incorporates the terms set forth in this **Section 2** and such other terms that are customary in agreements of a similar nature.

2.3 In the event that the Parties implement the New Process Strategy, Customer shall make the payments to Avecia that are described in **Appendix 2**.

3. TERM.

This Agreement shall take effect as of the Effective Date and shall remain in effect until the earlier of the date that is five (5) years after the date of Regulatory Authority Approval, or eight (8) years from the Effective Date (the “**Initial Term**”). Customer may elect to extend the term of the Agreement for an additional [*] period (the “**Extension Term**”), subject, if applicable, to an adjustment to the price of the Product in accordance with **Appendix 1** hereto, and provided that Customer provides Avecia with written notice of such extension at least [*] prior to the end of the Initial Term. Following the Extension Term, this Agreement shall continue in effect (“**Additional Term**”), subject to either Party terminating this Agreement at the end of the Extension Term or any Additional Term by giving the non-terminating Party written notice of such termination at least (a) where Customer is the terminating Party, not less than [*] prior to effective termination date, or (b) where Avecia is the terminating Party, not less than [*], as the case may be. The Initial Term, together with any Additional Terms, if applicable, may be referred to herein as the “**Term**”.

3.

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4. SALE AND PURCHASE; FORECASTS; MINIMUM ORDER SIZE.

4.1 Subject to the remaining provisions of this **Section 4**, Avecia agrees to manufacture and supply to Customer the quantities of Product set forth on written purchase orders submitted from time to time by Customer. Any purchase orders for Product submitted by Customer shall reference this Agreement and shall be governed exclusively by the terms contained herein. Any term or condition in any purchase order, confirmation, or other document furnished by Customer or Avecia that is in any way inconsistent with the terms and conditions set forth in this Agreement is hereby expressly rejected. During the Exclusive Period, Avecia shall sell to Customer and Customer shall purchase from Avecia, and, subject to **Section 4.3**, Customer shall and shall cause its Affiliates to purchase from Avecia (either directly or through Customer), [*] of the combined global commercial requirements of Product for Customer and its Affiliates for use in the prevention of hepatitis B. In addition, Customer shall, if Licensee elects not to manufacture Product itself, cause its Licensees to purchase from Avecia (either directly or through Customer), [*] of its combined global commercial requirements of Product for a minimum of (a) [*], or (b) for the remainder of the Exclusive Period, if less than [*] at the time of entry into the license with such Licensee. Except as required by the Rolling Forecast provisions of **Section 4.2** below, Customer shall not otherwise have any minimum purchase obligations under this Agreement. For the avoidance of doubt, the foregoing shall not prevent Customer from obtaining Product for use in research and development (including regulatory activities) from sources other than Avecia. If any such Licensee purchases Product directly from Avecia, such Licensee shall agree in writing as a condition of such purchase to be subject to the terms and conditions of this Agreement.

4.2 Within the first fifteen (15) days of each calendar quarter after Regulatory Authority Approval during the term of this Agreement, Customer shall provide to Avecia a written forecast of the requirement for Product of Customer (and, if applicable, of its Affiliates and Licensees) during such calendar quarter and the next succeeding three calendar quarters (the "**Rolling Forecast**"). The forecasted quantity with respect to the first calendar quarter of each Rolling Forecast shall constitute a firm commitment by Avecia to sell and Customer (either itself or, if applicable, through its Affiliates and/or Licensees) to purchase such forecasted quantity. The forecasted quantity with respect to the second calendar quarter of such Rolling Forecast shall be a firm commitment by Avecia to sell and Customer (either itself or, if applicable, through its Affiliates and/or Licensees) to purchase a minimum of [*] of such forecasted quantity. The forecasted quantity with respect to the third calendar quarter shall be a firm commitment by Avecia to sell and Customer (either itself or, if applicable, through its Affiliates and/or Licensees) to purchase a minimum of [*] of such forecasted quantity. The forecasted quantity with respect to the fourth calendar quarter of the Rolling Forecast shall be an indicative quantity with no commitment on either Avecia or Customer. Notwithstanding the above, Customer may submit to Avecia binding purchase order (s) for Product in excess of the amounts specified in a Rolling Forecast, and Avecia shall sell such quantity to Customer, subject to **Section 4.3** below. Notwithstanding the foregoing, Customer shall be permitted to reduce or eliminate any firm commitments established by Rolling Forecasts to the extent a decision of a Regulatory Authority prohibits or materially restricts commercial sale of the Product (or would reasonably be expected to have such an effect).

4.3 Customer shall order Product in Batch quantities. The parties agree that in order to allow campaign pricing, Customer may place an order for a campaign of Batches (at the time of the order of the Batch) that exceeds the then-forecasted quantities for the quarter covering up to a total of [*] of the forecast, and any such excess Batches ordered will be applied to the minimum purchase requirements for the successive quarters with respect to which such advance purchase is made by Customer. Except as set forth in the preceding sentence, the number of Batches ordered by Customer in any calendar quarter shall not exceed [*] Batches. Avecia shall not be required to manufacture Product in less than a [*] Batch campaign

4.

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under the Current Process and a [*] Batch campaign under the New Process. To the extent that Avecia does not agree to manufacture certain Batches pursuant to this **Section 4.3** or is otherwise unwilling or unable to manufacture Batches ordered by Customer, Customer shall be free to manufacture or have manufactured such Batches elsewhere.

4.4 If Avecia fails to deliver any Products in conformity with its obligations under **Section 4.2** above, Customer shall have the right to require Avecia to use expedited delivery methods to complete and deliver some or all of the relevant Products or cancel or any part of such order with respect to which delivery has failed. Further, should either Party perceive that a shortfall in delivery of Product by Avecia is likely to occur for any reason, the Parties shall discuss appropriate steps to alleviate such a shortfall. In the event that, over any [*] period, less than [*] of the Products ordered by Customer under this Agreement are delivered by the specified delivery date and in full compliance with the other terms and conditions of this Agreement (a “**Supply Failure**”), Avecia shall be deemed to, be in material breach of this Agreement. In addition, without limitation, in the event of a Supply Failure, the purchase requirements of Customer and its Affiliates pursuant to **Section 4.1** shall terminate upon such notice of a Supply Failure.

5. DELIVERY; TITLE; INVOICES; PAYMENT TERMS.

5.1 Upon the Product Release Date, Product will be delivered EXW (Incoterms 2000) Avecia’s facility in Milford, Massachusetts. For purposes of this Agreement, title and risk of loss in the Product shall pass to Customer on the earlier of (i) delivery to Customer’s designated agent or carrier and (ii) Avecia placing such Product in its GMP storage facilities for holding at the request of Customer. Prior to any storage of Product by Avecia for Customer, the Parties intend to negotiate and execute a separate storage agreement that will, among other things, specify their respective liabilities for loss or damage to stored Product.

5.2 Avecia shall issue invoices for Product on the Product Release Date for such Product and Customer shall pay, or arrange to have paid, to Avecia one hundred percent (100%) of the amount due under each such invoice by no later than thirty (30) days after Customer’s receipt of such invoice and the relevant release documentation.

6. PRICE; YIELD; SHELF LIFE.

6.1 The price for Product shall be determined in accordance with **Appendix 1**.

6.2 The price for Product hereunder excludes any applicable sales, use, consumption, value added or excise taxes, duties, tariffs and other similar assessments which may be imposed by any governmental authority as a result of the sale of Product hereunder. The Parties shall cooperate and take any reasonable, legally permitted steps to reduce or eliminate such charges.

6.3 A minimum acceptable yield per Batch will be established based upon process history. Standard yield will be initially determined after [*] Batches of Product have been produced at scale. For clarity, any Batch with a loss of Product extrinsic to the process and caused by Avecia’s negligence (for example, dropping a bottle of Product or spilling an in-process fraction or pool, rendering Product unusable) or failure to comply with the Product Requirements shall not be factored into the standard yield calculation. Yield shall be calculated on the moisture corrected quantity of Product after discharge from the freeze dryer.

6.4 Should, in any case, Avecia’s actual production yield be less than [*] of the defined standard yield, the price charged to Customer for the affected Batch(es) shall be [*], and Avecia shall

5.

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manufacture, upon Customer's request, an additional Batch beyond the forecasted quantity required to make up the difference; provided that Customer shall be obligated to purchase such full Batch at the established price for the Batch based on the forecasted campaign quantity. Customer may elect to have such make-up Batch deducted from the quantity of Product that it is required to purchase hereunder (e.g., as a result of a binding or partially binding portion of a Rolling Forecast) in the then current calendar quarter or the immediately succeeding calendar quarter.

6.5 Product delivered to Customer hereunder that is manufactured using the Current Process shall have at least [*] of its approved shelf life remaining at the Product Release Date, and Product delivered to Customer hereunder that is manufactured using the New Process shall have at least [*] of its approved shelf life remaining at the Product Release Date. Notwithstanding the foregoing, the remaining shelf life of Product delivered hereunder shall in all cases exceed (a) [*] or (b) the approved shelf life, whichever is lower.

7. ACCEPTANCE OF PRODUCT.

7.1 Within [*] of delivery of Product to Customer and except in the case of a Latent Defect, Customer shall notify Avecia of any claim for shortage of Product or that all or some of such Product does not meet Product Requirements. In the absence of such notification, such Product shall be deemed accepted by Customer as complete and in accordance with Product Requirements, subject to the following sentence. In the event of a Latent Defect, Customer shall have [*] from the date that Customer becomes aware of such Latent Defect to notify Avecia of any claim with respect thereto. In the absence of such notification during such period, such Product shall be deemed accepted by Customer as in accordance with Product Requirements even as to Latent Defects. Acceptance of Product by Customer shall not, by itself, limit Customer's rights under **Section 9.1**.

7.2 If Customer notifies Avecia in accordance with the provisions of **7.1** that Product does not conform to Product Requirement or that the amount of Product is less than the amount set forth in the applicable invoice, Customer shall advise Avecia of the manner in which Product does not conform to Product Requirements or shall document the shortage. In the event that Avecia accepts such determination, or if such determination is upheld by an independent laboratory or expert pursuant to **Section 7.3** (in the case of alleged non-conformance), or is confirmed pursuant to the dispute resolution procedures in **Section 22.3** (in the case of an alleged shortage); then Avecia shall deliver free of charge sufficient Product to make up such shortage or to replace defective Product, or at Customer's option shall refund the price of the missing or defective Product, and shall dispose of the defective Product at Avecia's cost.

7.3 If a dispute arises between the Parties as to any failure of Product to meet Product Requirements which dispute is not resolved by the Parties within thirty (30) days of the notice to Avecia that is described in **7.1**, either Party shall be entitled to require that the matter in dispute be referred to an independent laboratory or other appropriate expert nominated by agreement of the Parties. Such referral shall be solely for the purpose of establishing whether or not there is any failure of the relevant Product to meet Product Requirements. The decision of such independent laboratory or expert shall be binding upon the Parties, and the Party against which the decision is made shall be responsible for the costs of such independent laboratory or expert.

6.

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8. REPRESENTATIONS AND WARRANTIES.

8.1 Avecia represents and warrants to Customer as follows:

8.1.1 All Product conforms to and is produced in accordance with Product Requirements.

8.1.2 Avecia has, and will remain in material compliance with, all permits, licenses and other authorizations (the "**Permits**") which are required under USA federal, state and local laws, rules and regulations applicable to the manufacture, testing, storage, and/or handling of Product.

8.1.3 No person performing services on behalf of Avecia under this Agreement has been debarred under Section 306 of the United States Federal Food, Drug and Cosmetic Act or is otherwise excluded from any federal healthcare program. Avecia shall promptly inform Customer of any person performing services on behalf of Avecia under this Agreement becomes so debarred or excluded or is convicted of a crime that is grounds for such debarment or exclusion.

8.1.4 Manufacture of Product will be performed consistent with standards then customary in the oligonucleotide industry, and, in any event, with at least the degree of care and quality that Avecia uses to perform similar activities for other parties.

8.1.5 To the best of Avecia's knowledge, the Product and Avecia's manufacture of Product in the performance of this Agreement will not infringe the Intellectual Property or other rights of third parties.

8.1.6 Title to all Product provided to Customer hereunder shall pass to Customer as provided herein, free and clear of any security interest, lien, or other encumbrance.

8.2 Customer represents and warrants to Avecia that, to the best of Customer's knowledge (i) Customer has all rights necessary to permit Avecia to manufacture Product as contemplated in this Agreement, and (ii) Avecia's use of Customer's Intellectual Property in the performance of this Agreement will not infringe the Intellectual Property or other rights of third parties.

8.3 EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT. AVECIA AND CUSTOMER EACH EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS OF PRODUCT FOR ANY PARTICULAR PURPOSE.

9. INDEMNIFICATION; REMEDIES; LIMITATION OF LIABILITY; INSURANCE.

9.1 Avecia shall indemnify and hold Customer harmless from all losses, liabilities, damages and expense (including reasonable attorneys' fees and costs) incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) any breach by Avecia of the covenants, representations or warranties hereunder, or (ii) the infringement of the Intellectual Property rights of a third party arising from Avecia's manufacture of Product hereunder other than to the extent arising out of Avecia's use of Customer's Intellectual Property in its manufacture of Product hereunder; in each case (i) and (ii) above, other than to the extent caused by (a) any breach of the covenants, representations or warranties of Customer hereunder or (b) the gross negligence or willful misconduct of Customer hereunder.

7.

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9.2 Customer shall indemnify and hold Avecia harmless from all losses, liabilities, damages and expense (including reasonable attorneys' fees and costs) incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) any breach by Customer of the covenants, representations or warranties of Customer hereunder, (ii) the infringement of the Intellectual Property rights of a third party arising out of Avecia's use of Customer's Intellectual Property in Avecia's manufacture of Product or in the provision of other services for Customer hereunder, (iii) the use or sale of Product by Customer, Customer's Affiliates and Licensees, or by any third party or (iv) any use of Avecia's Intellectual Property in the manufacture of Product by a third party licensee of Customer; in each case (i) and (ii) above, other than to the extent caused by breach of the covenants, representations or warranties of Avecia hereunder or (b) the gross negligence or willful misconduct of Avecia hereunder.

9.3 Each Party will, at its own expense, obtain and maintain throughout the term of this Agreement, and for a reasonable and customary period of time thereafter maintain, (a) product liability and general liability insurance providing protection in the amount of (i) in the case of Avecia, at least [*] in aggregate and at least [*] per occurrence and (ii), in the case of Customer, at least [*] in aggregate and at least [*] per occurrence, and (b) workers' compensation insurance with not less than the minimum coverage limit as required by law. Each Party will furnish to the other Party, on an annual basis, a certificate of insurance or access to an electronic memorandum of insurance evidencing compliance with the provisions of this **Section 9.3**. In the case of Customer, the annual certification will state the total coverage held by Customer. The existence of such coverage will in no way limit either Party's liability or obligations expressly set forth under this Agreement.

9.4 EXCEPT FOR ITS INDEMNIFICATION OBLIGATIONS PURSUANT TO **SECTION 9.1(ii)** OR IN THE EVENT THAT IT IS FOUND THAT AVECIA ACTED GROSSLY NEGLIGENTLY, IN RECKLESS DISREGARD, OR IN WILLFUL MISCONDUCT, OR IF THE DAMAGES ARE FOR REPLACEMENT OR REPAYMENT OF MATERIAL THAT DOES NOT MEET THE WARRANTIES SET FORTH IN THE AGREEMENT, AVECIA'S LIABILITY FOR ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSES WHATSOEVER OR WITH RESPECT TO ANY PRODUCT SUPPLIED HEREUNDER SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, [*]; PROVIDED, HOWEVER, THAT SUCH LIMITATION SHALL NOT APPLY TO LOSSES OR DAMAGES ARISING FROM THE FRAUD OR WILLFUL MISCONDUCT OF AVECIA. IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT TO THE OTHER FOR SPECIAL, INCIDENTAL PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER THE CLAIM IS IN CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE.

10. INTELLECTUAL PROPERTY.

10.1 Nothing in this Agreement shall affect the ownership by either Party of any Intellectual Property or process owned by or in the possession of that Party as of the Effective Date or Intellectual Property developed independently of the work undertaken pursuant to this Agreement by any employee of that Party without reference to any of the Confidential Information disclosed by the other Party ("**Independent Intellectual Property**"). Other than giving Avecia the right to manufacture Product for Customer, nothing in this Agreement shall give either Party the right to use the other Party's Independent Intellectual Property.

10.2 All Intellectual Property generated, developed, discovered or invented by Avecia in connection with work conducted pursuant to this Agreement relating to the composition of matter of the Product shall be owned by Customer (such Intellectual Property called "**Customer-Owned Project IP**"). Any New Process and other Intellectual Property generated, developed, discovered or invented by Avecia

8.

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in connection with work conducted pursuant to this Agreement shall be owned by Avecia, provided that such Intellectual Property does not use or incorporate any Confidential Information of Customer (such other Intellectual Property called "**Avecia Owned Project IP**"), subject to the rights of Customer pursuant to **Sections 10.3** and **10.4**, Avecia hereby assigns and transfers to Customer all right, title and interest in and to the Customer-Owned Project IP and agrees to take all further acts reasonably required to evidence such assignment and transfer to Customer, at Customer's expense.

10.3 Avecia hereby grants to Customer a non-exclusive, irrevocable, worldwide, royalty-free license, with the right to grant sublicenses, under Avecia's interest in any Avecia-Owned Project IP (but not Avecia Independent Intellectual Property) to the extent that such Avecia-Owned Project IP is used in the manufacture of Product to make, have made, use, sell, import and export the Product and any improved Product.

10.4 Avecia hereby grants to Customer a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses, to Avecia's process to manufacture Product, which license shall be exercisable by Customer solely in the event that during the Term (i) Avecia ceases oligonucleotide manufacturing operations at the Facility, (ii) Avecia ceases its business operations generally, becomes insolvent or is the subject of a petition in bankruptcy or for reorganization or receivership, or ceases to function as a going concern or to conduct its operations in the normal course of business as previously conducted, or (iii) Avecia fails to supply the quantity of Product meeting Product Requirements for any reason other than a failure attributable to Customer (each, a "**Back-up License Event**"), and which license shall only be applicable to the extent of any shortfall of supply of Product resulting from the applicable Back-up License Event. In the event of a Back-up License Event, Avecia shall cooperate with Customer and/or Customer's designee in effecting the transfer of such technology to Customer or Customer's designee as is reasonably necessary to commence or continue commercial manufacture of the Product, and shall provide such technical assistance as Customer may reasonably require in connection therewith, at Avecia's expense. Such cooperation shall include Avecia's prompt assignment of any Third Party contracts with suppliers of materials, services, or equipment that are relevant to the manufacture of Product, or, where assignment is impractical because such Third Party is performing other services for Avecia under the same contract, Avecia shall take reasonable steps to facilitate a similar agreement between such Third Party and Customer directly. To ensure that the Parties are prepared should a Back-up License occur, at Customer's reasonable request, Avecia shall initiate the foregoing transfer of technology even if no Back-up License Event has yet occurred, it being understood that, unless and until a Back-Up License Event occurs, Customer's rights to Avecia's process to manufacture Product shall be limited to those activities necessary to accomplish and validate such technology transfer.

10.5 At Customer's request, Avecia agrees to bargain in good faith with respect to the grant to Customer of a non-exclusive worldwide license, with the right to grant sublicenses, to Avecia Independent Intellectual Property to manufacture Product, such license to take effect after termination of this Agreement (or at such other time mutually agreed by the parties) and to include commercially reasonable financial terms.

11. CONFIDENTIALITY.

11.1 In consideration of the Disclosing Party (Avecia or Customer, as the case may be) disclosing Confidential Information to the Receiving Party (Avecia or Customer, as the case may be), the Receiving Party hereby undertakes to maintain as confidential all such Confidential Information, and it will not use or disclose any of such Confidential Information in whole or in part save for purposes envisaged in this Agreement.

11.2 The foregoing restrictions on the Receiving Party shall not apply to any Confidential Information which:

(a) the Receiving Party can prove was already in its possession before the disclosure hereunder to it;

(b) is hereafter disclosed to, purchased or otherwise legally acquired by the Receiving Party on a non-confidential basis by or from a third party who has not derived it directly or indirectly from the Disclosing Party;

(c) is or becomes available to the public whether in printed publications or otherwise through no breach or default on the part of the Receiving Party, its agents or employees; or

(d) the Receiving Party can prove has been developed independently of the Disclosing Party by any employee of the Receiving Party without use of or reference to any of the Confidential Information disclosed by the Disclosing Party.

11.3 In order to secure the obligations under this **Section 11**, the Receiving Party agrees to exercise reasonable precautions to prevent and restrain the unauthorized disclosure and use of information subject to confidentiality, including restricting access to such information to such of its employees and representatives (i) as are bound to keep such information confidential and (ii) who need to have such access for the purposes of this Agreement.

11.4 The confidentiality obligations under this **Section 11** shall not apply to the extent that a Party is required to disclose information by applicable law, regulation or order of a governmental agency or a court of competent jurisdiction; provided, however, that such Party shall provide written notice thereof to the other Party, consult with the other Party with respect to such disclosure and provide the other Party sufficient opportunity to object to any such disclosure or to request confidential treatment thereof

11.5 The provisions of this **Section 11** shall survive termination or expiry of this Agreement and shall continue for a period of five (5) years from the date of such termination or expiry.

12. FORCE MAJEURE.

Neither Party is liable for any failure to perform or delay in performing any obligation under this Agreement, if such failure or delay is due to fire, flood, strike or any other industrial disturbance, war, embargo, legal prohibition, terrorism, insurrection, regulatory delay or any other cause beyond the reasonable control of such defaulting Party preventing or delaying the performance of such obligations. The Party so affected will, upon giving notice thereof to the other Party, be excused from such performance to the extent of such prevention, restriction or delay. Except in the case of strike or similar work stoppage, the affected Party is obligated to use its commercially reasonable efforts to avoid or remove such causes of non-performance and to continue performance with the utmost dispatch whenever such causes are removed.

Neither Party shall be entitled to relief under this **Section 12** for any delay or failure in performing any of its payment obligations under this Agreement.

13. TERMINATION; CONSEQUENCES OF TERMINATION.

13.1 Customer may terminate this Agreement upon [*] written prior notice to Avecia without further obligation in the event that the FDA or EMA requires manufacturing capability or quality levels for manufacture of the Product that Avecia is not then meeting, unless the Parties agree Avecia is able to meet any such requirements within such [*] period after written notice from Customer of such FDA or EMA requirement; and provided further that the parties shall discuss in good faith the continuation of this Agreement solely with respect to any other countries or territories in which such manufacturing requirements do not apply to the Product.

13.2 Without prejudice to any other rights or remedies which may be available to them, either Party may terminate this Agreement with immediate effect by giving written notice of termination to the other Party if the other commits a material breach of any of the provisions of this Agreement and, in the case of a breach capable of being remedied, fails to remedy such breach within [*] of receiving notice from the non-breaching Party specifying such and requiring the same to be remedied.

13.3 Subject to **Section 13.4** and without prejudice to any other rights or remedies which a Party may have, upon termination of this Agreement, howsoever the same occurs, each Party shall:

(a) immediately pay to the other all sums which at the date of termination are due and payable to the other hereunder;

(b) immediately cease all use of any property of the other, including, without limitation, any Confidential Information of the other Party; and

(c) at the expense of the requesting Party, promptly return to the other Party any property of the other in its possession, custody or control.

13.4 If (i) the Parties terminate this Agreement pursuant to **Section 13.1** or (ii) Avecia terminates this Agreement in accordance with **Section 13.2**, Customer shall purchase all amounts of Product which have been manufactured pursuant to Customer's orders but not yet delivered (at the price described in **Section 6**) and reimburse Avecia for (a) the reasonable, documented costs incurred by Avecia in connection with unfinished Product that is in the process of being manufactured or is in the Avecia manufacturing schedule as of the date of such termination (in each case pursuant to Customer's orders) and (b) Avecia's documented costs for any raw materials purchased in reasonable anticipation of meeting the firm commitment portion of the effective Rolling Forecast, provided these materials are not utilized by Avecia for other manufacturing. Customer shall have the right to take possession of any such raw materials or unfinished Product at its expense.

13.5 If Avecia terminates this Agreement under **Section 13.2** Avecia shall thereafter have the right to revoke any licenses granted under 10 (other than **Section 10.3**).

13.6 **Sections 1, 8.3, 9, 11, 13.3, 13.4, 14, 16, 20, 21, 22 and 23** shall survive the termination of this Agreement howsoever the same occurs. Termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either party prior to such termination.

11.

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14. REGULATORY; FACILITY ACCESS; AUDITS.

14.1 Avecia shall use commercially reasonable efforts to assist Customer in connection with obtaining any regulatory approvals with respect to Customer's products incorporating Products. Without limiting the foregoing, to the extent applicable, Avecia shall promptly furnish Customer with such information and documentation as Customer may request relating to, or necessary or useful for, any regulatory filings or submissions for Product. Avecia shall provide Customer with a copy of all proposed submissions to any regulatory agency associated with the manufacture of Product hereunder for Customer's review and approval.

14.2 Avecia shall permit Customer's employees, consultants and/or representatives to have reasonable access to the Facility for the purpose of verifying compliance with this Agreement and observing manufacturing and related activities, including access to relevant documents and records ("**Reasonable Access**"); provided such any disclosures to such persons shall be governed by **Section 11**.

14.3 Customer shall have the right to conduct, upon reasonable notice and at its own expense, periodic technical, quality, and environmental health and safety audits at the Facility. Avecia shall give Reasonable Access to Customer for purposes of auditing the Facility. Generally, four (4) and a minimum of two (2) calendar weeks' notice will be considered to be reasonable, but Avecia will provide Customer immediate access in case of rejections or emergency conditions.

14.4 Avecia shall cooperate with any inspection by the FDA or other regulatory authority relating to the Products. Avecia, if it is so aware, will promptly advise Customer if any regulatory authority intends to inspect the Facility and the nature of the inspection. Customer shall have the right to observe such inspection relating to the manufacture of Product. Avecia shall promptly provide a report of the results of such inspection to Customer. Avecia shall notify Customer promptly in writing in the event any action is taken or threatened by a regulatory authority relating to the manufacture or storage of Product, or relating to the Facility, or which may impair the ability of Avecia to supply Product in accordance with this Agreement.

15. ANNOUNCEMENTS AND PUBLICITY.

The Parties agree that, except as necessary to comply with applicable law or regulations, neither Party shall make any official press release, public announcement or other formal publicity relating to the transactions which are the subject of this Agreement, without first obtaining in each case the prior written consent of the other Party, which consent shall not be unreasonably withheld.

16. ASSIGNMENT AND CHANGE OF CONTROL.

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective legal successors but shall not otherwise be assignable by either Party without the prior written consent of the other Party; provided, however, that either Party, without the consent of the other Party, may assign this Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business and assets (or in the case of Customer, all or substantially all of its business and assets related to the Product for the prevention of hepatitis B), or in the event of its merger, consolidation, change in control or similar transaction. Customer may so assign its rights and delegate its obligations hereunder, without the consent of Avecia, to a licensee of Product, subject to Customer remaining liable to Avecia for the performance of such licensee's obligations under this

22.2 The Parties shall use reasonable efforts, acting in good faith, to reach consensus on all matters as expeditiously as possible. Should the Parties be unable to reach consensus on an issue, such issue shall be elevated to the respective presidents of each Party for resolution.

22.3 Any dispute not disposed of in accordance with **Section 22.2** shall be disposed of by binding arbitration under the rules of the American Arbitration Association. The arbitration shall take place in New York City, NY. The arbitrator shall be bound to follow the applicable provisions of this Agreement and Delaware law in adjudicating any dispute. It is agreed by the Parties that the arbitrator's decision is final, and that neither Party may take action, judicial or administrative, to overturn the decision. The judgment rendered by the arbitrator may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, either Party may seek equitable relief or interim or provisional relief from a court of competent jurisdiction if necessary to protect the interests of such Party or to preserve the status quo pending an arbitration proceeding.

23. ENTIRE AGREEMENT; AMENDMENT.

This Agreement and the exhibits attached hereto constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement, including without limitation the Confidential Disclosure Agreement between the Parties dated February 23, 2005. All information to be kept confidential under such earlier confidentiality agreement as of the Effective Date shall be maintained as Confidential Information by the receiving Party under the obligations set forth in this Agreement. In the event of a conflict between the terms set forth in the body of this Agreement and the terms of the Appendices attached hereto, the terms of this Agreement shall govern. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of each Party.

14.

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IN WITNESS WHEREOF, this Agreement has been entered into the day and year first above written.

NITTO DENKO AVECIA INC

DYNAVAX TECHNOLOGIES CORP.

By: /s/ Detlef Rethage
Name: Detlef Rethage
Title: President

By: /s/ Stephen Tuck
Name: S. Tuck
Title: V.P. Global Tech. Ops.

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APPENDIX 1

PRODUCT PRICE

Pricing is “campaign” based. Customer will order a minimum of [*] per campaign. Pricing for the current quarter’s production will be determined based on the binding portions of the rolling forecast. Avecia will consider all binding portions of the forecast which can be manufactured and delivered with the required stability to determine the price for the batches that will be delivered in the current quarter. Pricing will be adjusted quarterly based on the current rolling forecast. Customer has the ability and right to submit a PO for a quantity of batches beyond the number they have requested delivery for in one quarter. Thus providing them the means of securing a lower price than may be granted if based solely on the binding portions of the forecast.

Process Description	Price (\$k) on a [*] equivalence basis							
	[*] Batches	[*] Batches	[*] Batches	[*] Batches	[*] Batches	[*] Batches	[*] Batches	[*] Batches
Current Process @ [*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
New Process @ [*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
New Process @ [*] (if Nitto solid support can not be used)	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
New Process @ [*] (if heated C&D does not work)	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
New Process @ [*] (without Nitto solid support and without heated C&D)	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

Price will be inflated or deflated annually in line with a reputable externally published pricing index such as the US Producer’s Price Index for the Pharmaceutical Preparation Manufacturing Industry (“**PPI**”). “PPI” shall mean the US Producer Price Index for the Pharmaceutical Preparation Manufacturing industry (Series Id PCU325412325412).

For clarity, the Supply Price does not include any applicable sales, use, consumption, value added or excise taxes, duties, tariffs which shall be imposed by governmental authorities upon the material or the sale thereof.

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Potential Price Adjustment effective as of the beginning of the Extension Term.

In the event that Customer has notified Avecia, in accordance with **Section 3**, that it has elected to extend the term of the Agreement at the end of the Initial Term, and Avecia, within thirty (30) days of receiving such notice, reasonably demonstrates to Customer that the sum equal to (i) [*] of the applicable price per kilogram of such Product which would be effective as of the beginning of the Extension Term, the Parties agree that Avecia may increase such price as of the beginning of the Extension Term to not more than [*] of the otherwise applicable price; provided that, in lieu of accepting such price, Customer may elect to terminate this Agreement as of the end of the Initial Term.

2.

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NEW PROCESS STRATEGY

The New Process Strategy involves process changes to the Current Process as well as increasing the process scale from [*] per batch. It is planned that Customer with Avecia's support will seek specific regulatory advice/approval on the process change strategy.

The process change strategy to move Customer from the Current Process to the New Process contains 3 main elements:

1. Stage 1 - Definition and Demonstration of Process

a) [*].

2. Stage 2 - Preparation for Process Validation

a) [*].

3. Stage 3 - Execution of Process Validation

a) [*] {Redacted content comprises approximately 5 pages.}

3.

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APPENDIX 3

QUALITY AGREEMENT

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QUALITY AGREEMENT

**DYNAVAX TECHNOLOGIES
CORPORATION**

AND

NITTO DENKO Avecia Inc.

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A. DEFINITIONS

AGU - The AVECIA code for the oligonucleotide bulk material that is intended for use in a vaccine, and possesses immune stimulation activity. AGU is also referred to as 1018 ISS Adjuvant or 1018 ISS. AGU is regulated under 21 CFR 210/211, 21CFR600, and ICH Q7.

API - Active Pharmaceutical Ingredient.

Approved Vendor List - A list of approved vendors who have satisfied all the assessment criteria for approval set by AVECIA's Vendor Assurance Committee (VAC).

Batch Number - A controlled and unique identifier used to indicate a specific batch of AGU or Material.

Master Batch Record - A collection of approved procedures to be followed by AVECIA for the manufacture, testing, handling and storage of AGU. The Master Batch Record comprises the master manufacturing formula, raw materials and corresponding specifications, packaging and storage instructions and testing requirements.

BLA / MAA - A Biologics License Application filed with the United States Food and Drug Administration (FDA) to obtain marketing approval for Heplisav or any comparable marketing application (MAA) filed in countries outside the US to obtain marketing approval for drug product in that country.

BLA Supplement / MAA Variation - An application filed with the regulatory authorities (ie, FDA or EMA), to obtain approval for proposed manufacturing changes to drug product after approval.

Certificate of Analysis (COA) - A controlled document generated for each batch of AGU which certifies that AGU meets the approved manufacturing specifications and other agreed upon release criteria.

Certificate of Compliance (COC) - A document which is generated for each batch of AGU and which certifies that AGU was made in accordance with cGMP as defined by 21 CFR 211 and other relevant regulations.

Change Control - A process for the review and approval of Changes to a controlled document, equipment train, or process utility used to produce or control product(s) intended for use in drug product manufacture.

Editorial / Administrative Changes - This category involves changes that do not alter the process or product *per se* but relate only to documentation changes that are considered editorial. Such changes will generally not require prior approval by the Regulatory Authorities.

Minor Changes - These include modifications to procedures, process parameters, components, manufacture and manufacturing methods, reagents, equipment and facilities that have minimal potential to have an adverse effect on the product's identity, strength, quality, purity or potency as they may relate to

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its safety or effectiveness. Limited qualification or validation may be required for Minor changes. When the product is licensed by authorities, such changes will typically be reported to the Regulatory Authorities in the form of routine annual reports, and it may be necessary to amend regulatory filings as a result of such changes.

Moderate Changes - These include modifications to procedures, process parameters, components, manufacture and manufacturing methods, reagents, equipment and facilities that have a moderate potential to have an adverse effect on product's identity, strength, quality, purity or potency as they may relate to its safety or effectiveness. Moderate changes may require a regulatory action to the Authorities.

Major Changes - Changes in this category are considered significant and have a substantial potential to have an effect on product's identity, strength, quality, purity or potency as they may relate to its safety or effectiveness. Major changes, may require revalidation. Avecia Quality will notify Dynavax of Major Changes at the time they are first contemplated and before implementation. The implementation plan for such changes will be discussed in advance with Dynavax and should include provisions for process validation and demonstration of product/process consistency. AVECIA will provide Dynavax with the Change Notification Form at the time the change is first contemplated describing the change, its expected impact on product quality and implementation plan.

Emergency Changes - A change that is required to be implemented immediately by AVECIA to allow for continued processing or use of the facility. An Emergency change would usually be associated with a deviation.

Contractor - Any manufacturer, testing laboratory, packager, or other AGU support service provider, who performs testing, processing and/or packaging of AGU or its in-process intermediates.

Critical Equipment - Equipment that comes into contact with AGU or is essential to the manufacturing process or is designed to assure that AGU has the identity, strength, quality and purity that it is purported to possess.

Critical Observation - Any observation in an audit that if left uncorrected, could affect the safety of clinical subjects or patients or could reasonably result in an FDA-483, FDA warning letter, or other regulatory action.

cGMP - "cGMP" means current good manufacturing practices. As provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations to the US Code of Federal Regulations, Title 21 (21 CFR 210 and 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7, and subject to any arrangement, additions or clarifications agreed from time to time between the Parties in the Quality Agreement.

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Deviation - A departure from established procedures that is outside those covered by a Planned Deviation or Change. A Deviation does not permanently change an existing procedure and it must be investigated.

- **Major Deviation:** An event that has an impact or probable impact on the quality of AGU, or on the validated state of the manufacturing process, a system, or a test method; or requires regulatory reporting; or would have had probable impact without immediate corrective action (even if such action was taken and prevented such impact).
- **Minor Deviation:** An unplanned deviation that does not affect a reported result or the quality of AGU, or the validated state of the manufacturing process, a system or a test method.

Date of Manufacture - The date on which AGU is removed from the freeze dryer and packaged.

Facility - The site constructed and equipped by AVECIA in which AGU is manufactured.

FDA - The United States Food and Drug Administration or any successor entity thereto or any equivalent US or foreign governmental regulatory agency with jurisdiction to grant product license approvals,

Final Release - The release for further manufacture or processing by Dynavax QA of the bulk AGU. Final release signifies the material was produced using approved processes, is in compliance with regulatory submissions and applicable regulations, and meets its established specifications and quality attributes. It documents that all reviews, including by the manufacturer, have been completed and that any exceptions have been investigated and closed, as appropriate.

Formal Investigation - A written report detailing the specifics of an investigation resulting from an exception event, and which includes a description of the incident, investigation, conclusions, determination of root cause and corrective action or action plan, if applicable; as well as approval by Dynavax QA.

In-Process Specifications - The chemical, physical, biological and microbial testing methods and limits required for the clinical or commercial manufacture of AGU.

Joint Team (JT) - The Joint Team comprises primary points of contact for each company for technical consultation.

MAA (Marketing Authorisation Application) - Application for licensure in the European Union. Filing of the MAA gives EU inspectors the legal right to inspect all production, testing, packaging, and storage sites.

Manufacturer's Release - A Manufacturer's release is the documentation by AVECIA QA that a batch of AGU was produced using the approved processes, is in compliance with regulatory submissions and applicable regulations, and meets its established specifications and quality attributes. It documents that review has been completed by the AVECIA Quality Unit, and that any exceptions have been investigated

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and closed, as appropriate. Manufacturer's Release does not by itself permit the material to be used in humans.

Major Observation - Any observation listed, on FDA Form 483 or in a Deficiency Letter or any observation that may affect the safety, purity, integrity or strength of AGU.

Minor Observation - Any observation listed, on FDA Form 483 or in a Deficiency Letter which does not affect the purity, integrity or strength of AGU.

Material or Raw Material - Any excipients, or components, which are used in the manufacture of AGU.

Material Review Board (MRB) - A multidisciplinary committee responsible for the review, evaluation and disposition of non-conforming material.

Nonconforming Materials Report - A document used to describe the disposition of a raw material, in-process material or AGU that fails to meet established specifications, or is deemed Out-of-Trend.

OOS (Out-of-Specification) - A test result that lies outside of an approved specification or limit. If confirmed, the associated product lot is non-conforming.

OOT (Out-of-Trend) - Describes results that fall outside of the variance observed in previous batches or lots, or that are inconsistent with other data generated for the same lot. In a stability study, a result that is out of trend with results from previous time/temperature points or is not congruent with previous lot experience is out of trend.

PIP - Person in plant. A Dynavax employee or contractor that is allowed in the plant during the manufacture of AGU.

Planned Deviation - A change made to operating, manufacturing, or testing instructions or procedures planned and approved in writing by QA prior to implementation. Rationale for the change and project team consensus are normally obtained prior to opening of change control documentation. No planned change can be implemented without written QA approval.

Process - The procedure followed by AVECIA with respect to the manufacture, testing, handling and storage of AGU, consisting of a master manufacturing formula, instructions, qualification and delineation of raw materials, appropriate packaging and storage instruction and, testing requirements (specifications and method numbers).

Specifications for AGU - The chemical, physical, biological and microbial testing methods and limits required for the release of AGU provided that such specifications shall at all times comply with the regulatory filings made to the FDA or other regulatory agency in the country of sale.

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Confidential Information - Any technical, business, financial and other commercial information of a confidential nature disclosed (whether disclosed in writing, orally, by way of sample or by any other means and whether directly or indirectly) by either Party (the “*Disclosing Party*”) to the other Party (the “*Receiving Party*”).

Shipping Approval - Shipping approval is written documentation from DYNAVAX QA that a lot or lots are allowed to be shipped for further manufacturing or storage. AVECIA may not ship material without this documentation.

Stability Failure - A confirmed OOS result for a sample that has been stored under normal storage conditions (i.e., not accelerated) and that is within the current retest or expiry date of AGU. A potential stability failure occurs when trend analysis indicates that a given lot will go out of specification before the end of shelf life.

B. QUALITY REQUIREMENTS

Introduction and Purpose

This Quality Agreement is by and between NITTO DENKO Avecia Inc. (AVECIA), located at 125 Fortune Boulevard, Milford, Massachusetts 01757, and DYNAVAX Technologies, Corporation, located at 2929 Seventh Street, Berkeley, California 94710. Other projects will have separate quality agreements.

AVECIA provides contract GMP manufacturing and QC testing services, including: synthesis and purification of AGU, qualification of raw material and service vendors; release testing of raw materials; in-process monitoring, release and stability testing of AGU, and production support QC testing under cGMP for commercial use for DYNAVAX. This agreement outlines the respective quality roles and responsibilities of each party relating to the manufacturing, packaging/labeling, shipping and control of AGU intended for the manufacture of a vaccine intended for commercial distribution in the US and/or Europe.

Terms of Agreement

This Quality Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of AGU to DYNAVAX, unless an extension is requested in writing. Either party may terminate this agreement by giving 24 months written notice to the other party. Either party may propose changes to the existing Agreement at any time, and both parties will negotiate in good faith.

This Commercial Quality Agreement is pursuant to the Supply Agreement between AVECIA and DYNAVAX currently in existence. In the event of a conflict between any of the provisions of the Quality Agreement and the Supply Agreement, the terms of the Supply Agreement will prevail,

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

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In the event that Dynavax QA identifies a non-conformance with a lot of AGU, Dynavax QA will notify AVECIA of the specific item(s) that are non-conforming.

Assignment

Aside from a merger, consolidation, or a sale of all of a party's assets to a third party, neither party shall have the right to assign its rights or obligations of this Quality Agreement without the other party's prior written consent.

Confidentiality

AVECIA and DYNAVAX undertake to maintain as confidential all such Confidential Information, and neither will use or disclose any of such Confidential Information in whole or in part save for purposes described in this Agreement.

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

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B 1. Joint Team.

	AVECIA	DYNAVAX
	Quality Assurance	Quality Assurance
Name	JP Rodrique	Carmen Uy
Title	Director of Quality Assurance	Sr. Manager, QA
Phone	[*]	[*]
Fax	[*]	[*]
Email	[*]	[*]
Name	Janet O'Connor	William Turner (or designee)
Title	Director, Quality	VP, Regulatory Affairs and Quality Assurance
Phone	[*]	[*]
Fax	[*]	[*]
E-mail	[*]	[*]
	Quality Control	Quality Control
Name	Uditha deAlwis	Martin Gohlke, Ph.D.
Title	Director of Analytical Development	Director Analytical Development and Quality Control
Phone	[*]	[*]
Fax	[*]	[*]
E-mail	[*]	[*]

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	AGU Nonconformance/Complaints	AGU Nonconformance/Complaints
Name	JP Rodrique	Carmen Uy
Title	Director of Quality Assurance	Sr. Manager, QA
Phone	[*]	[*]
Fax	[*]	[*]
Email	[*]	[*]
	Manufacturing	Manufacturing
Name	Kelly Behrendt	Stephen Tuck
Title	VP of Operations	VP, Global Technical Operations
Phone	[*]	[*]
Fax	[*]	[*]
E-mail	[*]	[*]
	Regulatory	Regulatory
Name	JP Rodrique	Elaine Alambra
Title	Director of Quality Assurance	Director, Regulatory Affairs
Phone	[*]	[*]
Fax	[*]	[*]
E-mail	[*]	[*]

B 2. Provisions

This exhibit outlines the responsibilities of DYNAVAX (D) and AVECIA (A) with respect to the quality requirements of AGU intended for use in the manufacture of a vaccine for human use. AVECIA agrees to ensure that AGU is manufactured, tested, and given a manufacturer's release in compliance with approved specifications and in accordance with all applicable and EU cGMP standards. The Quality Agreement is divided into the following sections:

Quality Systems

Facilities and Equipment Systems

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- Material System
- Production System
- Packaging, Labeling and Distribution System
- Laboratory System

The following tables define the quality roles and responsibilities of each firm. Means of performance and minimum standards are indicated in the column labeled “**Deliverables**”.

Term	Definition
A	Avecia
D	Dynavax
Responsibility (X)	Performs activity and ensures sustained compliance for day-to-day activities. Directly responsible for compliance.
Oversight (O)	Monitors and provides reasonable support and guidance to assure compliance requirements are met for cGMP. Accountable to regulatory agencies. Assures it by audits, person in plant (PIP) or documented review or approval as indicated.

B 3. Quality Systems

Description	A	D	Deliverable or Means
B 3.1 General Compliance			
a. Manage and maintain the Quality Agreement. Update needed by providing a red-lined draft and request for change.	O	X	Written, signed Agreement
b. Implement the Quality Agreement and train staff as needed on the terms of the Agreement.	X	X	
c. Quality Unit has the responsibility to assure that the quality systems are in place, and effective for the manufacture of AGU.	X	O	Audits, PIP, document reviews and approvals
d. AVECIA Quality Assurance will notify DYNAVAX Quality Assurance in writing regarding any deviation, OOS, or exception that may impact AGU quality or GMP compliance. AVECIA will work with DYNAVAX Quality Assurance to arrive at a mutually acceptable procedure to take appropriate action.	X	O	Send within 2 AVECIA business days for majors, deviations and [*] business days for minor deviations.

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Description	A	D	Deliverable or Means
e. Agree upon, implement, and maintain specifications and in-process control tests for the AGU production processes. Changes must be mutually agreed upon and controlled by means of a GMP change control system. Specification changes must be approved by and communicated in writing to the Quality Unit,	X	X	Change control system and specifications committee
f. Changes in compendial methods or specifications shall be made by AVECIA to stay in compliance with the current USP and Ph. Eur. Compendia. Sponsor approval is not required. (Note: If such changes impact Avecia Quality Test Methods or specifications filed for AGU, then Dynavax approval is required prior to initiation).	X		Written notification to DYNAVAX QA within [*] of making change, but approval not required.
g. AVECIA certifies that the facility and equipment used for the manufacture of AGU are not utilized for the production of cytotoxics or antibiotics, including penicillins, cephalosporins, carbacephems, monobactams, or other beta-lactam antibiotics as described in the Draft Guidance for Industry, Non-Penicillin Beta-Lactam Risk Assessment: A cGMP Framework, March 2011,	X		Verified during audits.

Description	A	D	Deliverable
B 3.2 Regulatory			
a. Act as Sponsor, ie hold the regulatory registrations for drug products produced using AGU, and be the contact for Agency communications and updates regarding AGU.		X	BLA, MAA, Agency communications files (Regulatory Affairs)
b. Maintain and operate the Facility in compliance with the applicable laws, standards, and current regulatory requirements. Maintain all applicable licenses, registrations, and certifications needed for the facility and AGU manufacture.	X		Notify DYNAVAX QA of any license suspensions or other significant changes in writing within 30 days of detection

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Description	A	D	Deliverable
c. DYNAVAX shall provide AVECIA the opportunity to review significant information related to the manufacture and/or control of AGU before it is submitted to regulatory authorities.		X	Supply draft of AGU regulatory information for review. Provide a copy of the applicable license application sections submitted.
d. DYNAVAX QA/RA shall notify AVECIA QA in a timely manner of all regulatory approvals or application withdrawals relevant to AGU.		X	Within [*] business days of Dynavax knowledge
e. AVECIA QA shall notify DYNAVAX QA promptly of any regulatory inspection findings related to AGU or that have significant impact on AVECIA's ability to manufacture AGU for DYNAVAX.	X		Within [*] business days of AVECIA knowledge
f. AVECIA QA shall notify DYNAVAX QA immediately of any (confirmed) stability failure or potential stability failure for storage temperature, to permit timely notification to regulatory authorities (72 hrs in some cases).	X		Within [*] business day of observation; request notification when investigation opens

Description	A	D	Deliverable
B 3.3 Regulatory Agency Inspections			
a. AVECIA QA shall inform DYNAVAX QA, of any significant communication or action (e.g., telephone call, record or sample request, recall, etc.) initiated by a regulatory agency (US or international) as it affects the manufacturing of AGU.	X		Notification in no more than [*] business day
b. DYNAVAX QA/RA shall inform AVECIA of any significant communication or action (e.g., telephone call, record or sample request, recall, etc.) initiated by a regulatory agency (US or international) as it affects the manufacturing of AGU.		X	Notification in no more than [*] business day

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Description	A	D	Deliverable
c. Planned inspection of AGU: AVECIA to notify Dynavax as soon as reasonably possible in writing to Dynavax QA; and permit Dynavax personnel to be on-site as needed. Dynavax staff shall not represent AVECIA to any inspectors, and AVECIA reserves the right to exclude Dynavax staff from direct contact with inspectors.	X		Within [*] business days of AVECIA knowledge
d. Unannounced inspection related to AGU: AVECIA to notify Dynavax QA as soon as possible in writing.	X		Within [*] business day

Description	A	D	Deliverable
B 3.4 Training – GMP			
a. AVECIA will maintain and follow a documented procedure describing training requirements.	X	O	Confirm in audit
b. An adequate number of qualified AVECIA personnel will be available to perform and supervise the plant start-up, manufacture, processing, testing, Quality Control and Quality Assurance of AGU.	X	O	Confirm in audit

Description	A	D	Deliverable
B 3.5 Documentation and Records			
a. Systems will be maintained for the generation of master batch records, Standard Operating Procedures (SOP), validation protocols, validation reports, QC controlled records, and documentation to support the manufacturing process and associated systems.	X	O	DYNAVAX to have signature approval of all product-specific documents and ability to audit GMP documentation except for that dedicated to other clients.
b. AVECIA will maintain a traceable index of all records pertaining to the manufacture of AGU in a secured storage location and container whether archived on site or off-site.	X		Readily available during business hours, if onsite, and within [*] if offsite.

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Description	A	D	Deliverable
c. AVECIA will ensure that all records are maintained throughout the lifetime of this agreement, and for 10 years thereafter (or records are sent to DYNAVAX for archiving), in accordance with a documented record retention program.	X		Retention period shall be [*] post termination; AVECIA to contact DYNAVAX QA in writing before destroying any documents related to AGU.

Description	A	D	Deliverable
B 3.7 Electronic Records and Record Systems Control and Security			
a. AVECIA is responsible for the compliance of electronic record systems that are used in the production of DYNAVAX AGU and to assure 21 CFR, Part 11 or Annex 11 compliance where applicable.	X	O	Deliverable on Audit: Copy of FDA Part 11 letter, list of validated electronic systems, risk assessments.

Description	A	D	Deliverable
B 3.8 Audits			
a. DYNAVAX and its affiliates or potential partners have the right to audit AVECIA manufacturing facilities and systems, as they relate to the manufacture of AGU, with the exception of information and operations regarded by AVECIA as Proprietary Information. Unless for cause, number of audits of AVECIA not to exceed one audit per year except for additional mutually agreed upon visits.	O	X	Audit schedule or plan
b. Access to contract manufacturing facilities for AGU audits will be granted subject to facility availability. Requests should be directed to the AVECIA QA department.	X	O	Inspection requests must be received no less than [*] prior to the requested date for the audit. In the event of a “for cause” audit, one week notice is required.

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Description	A	D	Deliverable
c. During the audit, DYNAVAX QA may review records and documents to assess suitability and compliance of the Quality Systems and AGU/process. AVECIA has the right to redact if necessary, to protect proprietary interests of its clients and contractors.	X	X	Audit and PIP
d. DYNAVAX QA will document audit observations in a confidential audit report and provide to AVECIA QA in a timely manner.		X	Report issued within [*] business days from date of audit completion, unless an alternate time frame is agreed upon.
e. AVECIA will issue a written response to the audit report, including action plan, to DYNAVAX QA, in a timely manner.	X		Response within [*] business days of receipt of the report, unless an alternate time frame is agreed upon.
f. DYNAVAX will work with AVECIA to arrive at a consensus plan to address any observations considered to be major or critical. AVECIA will propose timelines and notify DYNAVAX of significant delays in implementation.	X	X	As needed, proposed actions will be reviewed by the Joint team. Any delays in implementation over [*] from due date shall be reported and justified to Dynavax QA in writing.

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Description	A	D	Deliverable
B 3.9 Change Control			
<p>a. AVECIA will maintain a documented change control procedure for the control of changes to manufacturing materials and components, critical equipment or utilities, packaging materials, labeling, manufacturing methods, AGU and in-process specifications, test methods and vendors.</p> <ul style="list-style-type: none"> • Editorial changes will be communicated to Dynavax by a change control notification. (eg. Examples: change to the company name of a raw material supplier; correction of typographical errors) • Minor Changes will be communicated to Dynavax by AVECIA via the Change Control Form for approval prior to implementation. This notification must include a rationale describing why the change is expected to have minimal impact on product quality. (eg. Example: addition of a new supplier for a non-critical raw material) • Moderate Changes at the time they are first contemplated describing the change, its expected impact on product quality, the implementation plan and timing. All Moderate Changes will be communicated to Dynavax by AVECIA via the Change Control Form for formal approval prior to implementation. Post implementation of the approved plan, AVECIA will provide, as applicable, supporting documentation including validation data, test samples and additional test methods, as appropriate to support regulatory actions. (Example: addition of a new supplier for a critical raw material.) 	X	O	<ul style="list-style-type: none"> • Editorial - within [*] of implementation. • Minor – review and approval of submitted Change Control by DYNAVAX. • Moderate – Review of the Change Control and justification prior to implementation. • Major – Review of the Change Control and justification prior to implementation. Mutual agreement on timing of implementation based on regulatory submission timing.

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Description	A	D	Deliverable
<ul style="list-style-type: none"> Major Changes will be communicated to Dynavax by AVECIA via the Change Control Form for formal approval prior to implementation. Post implementation of the approved plan, AVECIA will provide, as applicable, supporting documentation including validation data, test samples and additional test methods, as appropriate to support regulatory actions. Major changes usually require a submission to the regulatory authorities and their approval before a product manufactured with the change is distributed to the market, (e.g. Example: Change to a critical raw material such as change to a new type of solid support.) 			
<p>b. Changes to facilities, utilities, and other items that are not part of the description in a regulatory filing and do not require a BLA/MAA amendment notification of the change is sent to DYNAVAX. See Change Control definition for minor, moderate and major changes.</p>			b. Within [*] calendar days of implementation.
<p>c. The respective quality units must approve planned change proposed by DYNAVAX or AVECIA that has the potential to impact the quality, purity, safety, effectiveness or regulatory status of the AGU prior to implementation.</p> <ul style="list-style-type: none"> Editorial Minor Moderate Major Emergency Change implemented by AVECIA that is a Moderate or Major change classification. 	X	X	<p>A written response is required that is signed by the respective QA unit within:</p> <ul style="list-style-type: none"> Notification only Within [*] business days Within [*] business days Within [*] business days Within [*] of change occurring

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Description	A	D	Deliverable
d. Approval must occur through change control for any prospective change in the manufacturing, process, potentially affecting a regulatory filing, test, equipment, software changes or implementation, facilities, specification, formulation process instruction, raw material and supplier, process validation, labeling content or position, storage condition, critical in-process control including equipment operational setting or critical alarm, or any other item in any manner that would impact the manufacturing or processing activities to be performed by AVECIA. See section (a.) above for details.	X	X	DYNAVAX to approve all changes that may impact a validated process or validated dedicated equipment. DYNAVAX to determine a mutually agreed regulatory pathway
e. Determination must be made as to the regulatory filing requirements of all changes: For example: annual reportable, CBE 30, Pre-approval supplement, or Type C meeting, license variations, etc.		X	DYNAVAX Regulatory Affairs to determine regulatory impact of changes.
f. Avecia will notify Dynavax of the introduction of new products within the current 'chemical families' (ie, similar potency, safety, dose, etc) into the licensed AGU facility, with sufficient documentation to support the Avecia determination that the new product(s) are similar to existing products produced in the facility.	X		[*] working days for review by Dynavax

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Description	A	D	Deliverable
<p>g. As required by regulatory agencies, Avecia will notify Dynavax of the introduction of a new family of products, or a product that may be within the current family but that has a therapeutic indication with a significantly different potency, dose, safety, etc., into the licensed AGU facility with sufficient documentation to support the Avecia assessment of the risk of introduction of the product into the facility.</p> <p>Documentation may include:</p> <ol style="list-style-type: none"> 1. The controls in place at Avecia to prevent contamination, cross-contamination, mix-up and line clearance 2. Location in Avecia of the new product manufacture and storage with respect to AGU 3. List of equipment that will be shared with AGU and associated cleaning validation, procedures and processes <p>As required by regulatory agencies, Dynavax will file the required notification to the BLA/MAA for the product that will be introduced into the facility where AGU is manufactured no less than 30 days prior to the manufacturing date of the new product. A copy of the notification will be sent to Avecia.</p>	X	X	[*] days for review by Dynavax Allowing [*] days prior to introducing the new product into the facility if FDA notification is required.

Description	A	D	Deliverable
B 3.10 Deviations			
<p>a. AVECIA will utilize approved procedures to detect, document, and investigate deviations and exceptions. The procedures should include CAPA processes for batch specific corrective actions and for long-term preventive actions along with a provision for assuring the performance of adequate and appropriate failure investigations.</p>	X	O	DYNAVAX to be notified in accordance with B3.10b

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Description	A	D	Deliverable
b. AVECIA will notify DYNAVAX QA of any Deviation, non-conformance, or investigation that may potentially impact the quality, safety, purity, and integrity of AGU. Stability failure and potential stability failure are major events and require immediate notification to DYNAVAX QA. Dynavax QA must approve all major deviations/ investigations.	X	O	Within 2 AVECIA business days for major events, 5 AVECIA business days for minor
c. AVECIA shall notify DYNAVAX QA of deviations and investigations for other products or equipment that may impact the ability to manufacture AGU.	X	X	Information may be redacted as needed.

Description	A	D	Deliverable
B 3.11 Investigation			
a. AVECIA will investigate and report to DYNAVAX whenever AGU fails to meet specification, or there is significant uncertainty in conformance with the cGMPs.	X	O	Written notification to the project contact and QA Within [*] business day of confirmation.
b. DYNAVAX will report to AVECIA whenever there is a failure to meet specifications or compliance based on a DYNAVAX review.	O	X	In writing. from QA to QA, within 30 days of confirmation
c. When an OOS or OOT result is observed, AVECIA shall notify DYNAVAX QA promptly, open a formal investigation according to its procedures, and report the findings in writing. AVECIA shall not perform any re-sampling or re-testing without approval of DYNAVAX QA, unless laboratory or sampling error is confirmed and the OOS result is invalidated.	X		Notify JT contact and QA Dynavax within 3 AVECIA business days of detection; in general, report to quality unit within 30 days.

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Description	A	D	Deliverable
B 3.12 AGU Complaints			
a. DYNAVAX QA will notify AVECIA QA as soon as reasonably possible of any customer complaints that may be associated with the manufacture, storage, and handling of AGU.		X	Notification within [*] AVECIA business days
b. AVECIA QA will work with DYNAVAX QA to conduct internal investigations to determine the validity of the complaint.	X	X	QA, other Dynavax subject matter experts as needed
c. AVECIA QA will remediate the issue associated with the complaint as it relates to AGU.	X		AVECIA will submit investigation report to DYNAVAX QA
d. DYNAVAX QA will be responsible for customer response communications and will submit a copy to AVECIA QA.	O	X	Within [*] of issuance

Description	A	D	Deliverable
B 3.13 Field Alerts and Recalls			
a. DYNAVAX will notify AVECIA of confirmation of the event, by telephone or other rapid communication means, when there is information concerning any AGU issues that may impact the quality, purity, safety and effectiveness of AGU. Examples of such information include a stability failure of drug product or any significant chemical, physical or other change or deterioration in the distributed AGU.		X	Notification within [*] business days
b. In the case where a field alert, withdrawal, or recall is necessary and the manufacture of AGU may have contributed to the cause of such event, a strategy for investigating the potential cause will be defined by DYNAVAX and AVECIA.	X	X	Site visit, QA/RA; for-cause QA audits within [*]

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B 4 Facilities and Equipment Systems

Description	A	D	Deliverable
B 4.1 Process Qualification and Validation			
a. AVECIA will perform appropriate installation qualification (IQ), operational qualification (OQ), and/or performance qualification (PQ) for the required classes of equipment used and process used for the production and control of AGU. Evaluation and/or re-validation will be conducted in accordance with appropriate specifications/ procedures.	X		Confirm in audit
b. Documentation of such activities and/or schedule of revalidation shall be the responsibility of AVECIA.	X		Confirm in audit
c. Documentation shall be available to DYNAVAX or partners, upon mutual agreement with AVECIA, or Regulatory Authorities upon request.	X		
d. Copies of AGU specific documentation will be made available at the request of DYNAVAX.	X		
e. AVECIA commits to re-qualify equipment and systems if changed and determine the impact on current process in accordance with AVECIA change control policies. This shall be done by AVECIA prior to future manufacturing.	X		Change control or change notification system

Description	A	D	Deliverable
B 4.2 Equipment, Calibration and Preventive Maintenance			
a. AVECIA will have appropriate procedures in place for calibration and maintenance of equipment utilized in the manufacture, testing and release of AGU.	X		Confirm in audit
b. AVECIA will maintain documented calibration and preventive maintenance programs to support the manufacture and validation of AGU.	X		Confirm in audit

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Description	A	D	Deliverable
B 4.3 Process Qualification/Validation			
a. AVECIA will ensure that the process, manufacturing, testing and control procedures (including cleaning procedures, hold times, mixing studies, etc.) are qualified or validated in accordance with established protocols and procedures utilizing equipment and personnel in the facility intended for manufacture of AGU.	X	X	Dynavax must approve the protocols and reports.

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B 5. Material System

B 5.1 Evaluation/Qualification of Contractors and Suppliers			
Description	A	D	Deliverable
a. AVECIA will utilize a documented supplier qualification procedure for the approval of raw material and component suppliers. The program will include establishment of component and raw material specifications, assessment of the supplier, and testing of lots of each raw material as required. The acceptance criteria will include at a minimum, the demonstration of the presence and execution of quality systems sufficient to meet established component, raw material, In-Process and AGU Specifications and a process for ongoing vendor assessment and response.	X	O	List of suppliers, dates of qualification, and raw material qualification data available during audits or upon request
b. AVECIA will maintain raw material specifications and COAs, as well as any associated certificates (such as Certificate of Suitability) for all raw materials used in the manufacture of DYNAVAX AGU. AVECIA shall not change the supplier, manufacturing process or the quality grade of any critical raw material without approved change control documentation from DYNAVAX.	X		Change control system
c. AVECIA shall notify DYNAVAX in writing if contractors or subcontractors are used to perform stability, in-process or final product testing. These may not be changed without approved change control from DYNAVAX QA.	X	O	DYNAVAX approval through AGU Specification approval

Description	A	D	Deliverable
B 5.2 AGU Storage			
a. AVECIA will maintain adequate storage areas for quarantine, rejected and released AGU.	X		

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Description	A	D	Deliverable
b. AVECIA will store AGU under conditions appropriate to maintain the quality, safety, purity, and integrity of AGU in accordance with cGMP requirements.	X		Qualification of storage facility or equipment
c. AGU will be stored under conditions specified in AGU labeling and in a controlled area. Records demonstrating adherence to specified storage conditions will be retained and available for audits.	X	O	Monitoring trends
d. In the event of an environmental outage or deviation, AVECIA shall notify DYNAVAX of such an event and ensure that documentation of the outage and subsequent investigation is reviewed and the impact evaluated. Copies of such documentation will be supplied to DYNAVAX upon request or provided within the batch records.	X	O	Within two (2) AVECIA business days

B 6. Production System

Description	A	D	Deliverable
B 6.1 Manufacturing Process			
a. AVECIA will ensure that AGU is manufactured and tested in compliance with cGMP, and in accordance with approved Batch Records, procedures and validated methods, as well as within accordance of any regulatory license parameters	X	O	COA, COC, batch record. TSE certification as needed

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Description	A	D	Deliverable
B 6.2 Reprocessing, Rework, and Re-inspection			
a. DYNAVAX does not intend to reprocess or rework AGU at this time. In the event that this is proposed, AVECIA and DYNAVAX must define how reprocessing or reworking will be done in a validation protocol. DYNAVAX QA and RA written approval is required prior to the start of any reprocessing or reworking.	X	X	Protocol, master batch record and justification.

Description	A	D	Deliverable
B 6.3 Executed Batch Records			
a. Summaries of all AGU testing, lot release data and Deviations will be documented in the Batch Record and an electronic copy provided to DYNAVAX for review.	X		Copy of executed Batch Record and related records as required
b. AVECIA will maintain original executed Batch Records in accordance with AVECIA retention requirements.	X		AVECIA to contact DYNAVAX QA prior to destroying any records
c. AVECIA manufacturing and quality assurance personnel will review and approve all executed Batch Records, including for any failed or aborted batches. These records shall be consistent with the Process Description and all regulatory filings.	X		Generally within [*] Business days of DOM
d. AVECIA will send DYNAVAX copies of executed batch records and associated testing data for all batches, including batches that were rejected by AVECIA.	X		Within [*] business days of manufacturer's disposition
e. DYNAVAX QA will review executed batch records with associated QC and environmental monitoring data (if applicable) and notify AVECIA QA of any batch record deficiencies. AVECIA will assess and amend or clarify records as needed, providing update to DYNAVAX QA and including the revised pages.		X	Within [*] business days of AVECIA manufacturer's release. Or date received, whichever is longer.

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Description	A	D	Deliverable
B 6.4 AGU Testing and Lot Release			
a. AVECIA will perform AGU testing and manufacturer's release in accordance with qualified or validated methods against the Dynavax approved specifications for AGU.	X		CoA and CoC.
b. AVECIA will verify compendial methods before putting them into use, and will manage changes in the compendia to assure compliance with the current monographs.	X	O	Confirm in audit
c. Non-compendial methods will be transferred as needed and validated by AVECIA in accordance with DYNAVAX's method transfer protocols.	X	X	As needed
d. AVECIA will transfer in and validate methods developed at other contract laboratories in accordance with their standard operating procedures. Dynavax QA must approve the protocols and reports for methods specific to AGU.	X	X	As needed
e. AVECIA will validate/qualify as appropriate applicable methods for environmental monitoring, in process, and bulk AGU testing, to meet current ICH standards and regulatory requirements. Dynavax QA must approve the protocols and reports for methods specific to AGU.	X	X	As needed

Description	A	D	Deliverable
B 6.5 Responsibility for Final Release of AGU			
a. AVECIA QA will assure that AGU has been manufactured in accordance with cGMP's (provide certificate), deviations were resolved and specifications were met.	X	O	Certificate of compliance Certificate of analysis Summary of deviations

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Description	A	D	Deliverable
b. Final release for further use or disposal of AGU is the sole responsibility of DYNAVAX QA.		X	Release statement
c. AGU may not be shipped from AVECIA without a signed authorization from Dynavax QA.		X	Memo or release statement

Description	A	D	Deliverable
B 6.6 Lot Failure			
a. AVECIA agrees to notify DYNAVAX of any AGU lot failure upon confirmation of that failure, as soon as reasonably possible.	X		Within one (1) business day.
b. DYNAVAX will assess the impact of all failures on previous lots that have been produced and will notify AVECIA immediately if the failure impacts any lots shipped or accepted by DYNAVAX.	O	X	Notification within one (1) business day

Description	A	D	Deliverable
B 6.7 On Site Personnel (Person-in-Plant)			
a. AVECIA shall allow DYNAVAX to have qualified personnel (quality and/or manufacturing) on site during the manufacturing of AGU in a location and to a scope agreed to by both parties. AVECIA has the right to control plant access and number of personnel to protect its facility and the product.	O	X	(PIP)

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B 7. Packaging, Labeling, and Distribution System

Description	A	D	Deliverable
B 7.1 Shipping & Receiving			
a. AVECIA will prepare AGU for shipment using validated conditions appropriate to maintain the quality, safety, purity, or integrity AGU.	X		Shipping validation and specification of package configuration and instructions
b. Copies of shipping information, including temperature monitoring data, if applicable, will be retained for each lot of AGU shipped in accordance with AVECIA procedures.	X		Shipping packet; temperature data

B 8. Laboratory System

Description	A	D	Deliverable
B 8.1 Testing			
a. AVECIA is responsible for conducting stability studies for AGU as specified in stability study protocols approved by both parties.	X	X	Protocol and report
b. Sample storage shall be maintained in compliance within the stated temperature ranges.	X		Report deviations to DYNAVAX QA in writing as per SOP
c. AVECIA agrees to notify DYNAVAX of any Out-of-Specification (OOS), Out of Trend (OOT) or other unexpected results upon confirmation of that result, as soon as reasonably possible. Written investigation report shall be provided within 5 working days of the close of investigation, or with the associated batch record.	X		Notify DYNAVAX QA as defined in B.3.10.b.
d. AVECIA agrees to immediately notify DYNAVAX of a stability failure, i.e. an OOS within the shelf life of AGU.	X		As soon as possible; generally within 1 AVECIA business day.
e. Trending of stability data and assignment of re-test or expiration dates will be performed by Dynavax. Dynavax to inform AVECIA of the re-test or expiration date changes to AGU.		X	

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Description	A	D	Deliverable
B 8.2 Samples			
a. AVECIA shall be responsible for ensuring that the number of retain samples maintained shall be sufficient to perform all release testing in duplicate, if necessary, upon confirmation with DYNAVAX.	X		
b. AVECIA or a site designated by DYNAVAX shall retain samples of each lot of AGU for at least a period of one (1) year after the expiration date of the last packaged AGU manufactured with such lot unless otherwise requested by DYNAVAX.	X	O	DYNAVAX to track dating and inform AVECIA annually
c. AVECIA shall notify DYNAVAX QA prior to destroying any retain samples	X	O	In writing, at least 30 days in advance

Description	A	D	Deliverable
B 8.3 Quality Control (QC) Samples			
a. AVECIA shall conduct environmental monitoring, testing of incoming raw materials, in-process and release testing as defined in section B 6.4 of this document for each lot of AGU. QC samples will be obtained and tested in accordance with established sampling and testing methods.	X	O	

Description	A	D	Deliverable
B. 8.4 Certificates of Analysis			
a. AVECIA Quality Assurance will generate and sign a certificate of compliance (COC) for each lot released. For a rejected batch, AVECIA shall provide written notice as well as the executed batch record.	X		COC; executed batch record

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Description	A	D	Deliverable
b. A Certificate of Analysis (COA) will be generated by AVECIA for each batch of AGU manufactured for DYNAVAX.	X		COA
c. The COA will certify that AGU meets the release testing specifications agreed between AVECIA and DYNAVAX. COA's for AGU will contain the following information: <ul style="list-style-type: none"> • AGU • Lot number • Date of manufacture • Site of manufacture • Test Method (Name of test and number) • Specification limits • Test result as a numerical value unless designated Pass/Fail, not detected, or as a qualitative result in the specification limit 	X		
d. AVECIA Quality Assurance will approve and date the COA and provide to DYNAVAX QA. Both firms understand that this constitutes Manufacturer's release and not a final release for use in manufacture of vaccine for human use. Until or unless a final release is received from DYNAVAX QA, the material must be handled under quarantine.	X		
e. Dynavax QA will notify AVECIA QA and provide a final release within twenty one (21) working days of AVECIA releasing the lot of AGU.		X	Lot Disposition Form

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Description	A	D	Deliverable
B 8.5 Reference Standards			
a. AVECIA will supply sufficient amounts of analytical reference standards for AGU and its known impurities to qualify and conduct AGU release testing. Such standards shall be characterized. See Appendix 1 .	X	O	AVECIA to take [*] of a mutually agreed upon lot and characterize as primary reference standard. See Appendix 1 for impurities.

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C. SIGNATURE PAGE

William Turner, Vice President, Regulatory Affairs and Corporate QA, DYNAVAX Technologies

/s/ William Turner

Signature

Date: 12 Sep 2012

Jeanne Bonelle, Sr. Director, Corporate QA, DYNAVAX Technologies (acting)

/s/ Jeanne Bonelle

Signature

Date: 12 Sep 2012

Detlef Rethage, President, NITTO DENKO Avecia, Inc.

/s/ Detlef Rethage

Signature

Date: 12 Sept 2012

JP Rodrique, Director, Quality Assurance, NITTO DENKO Avecia, Inc.

/s/ JP Rodrique

Signature

Date: 12 Sep 2012

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D. APPENDICES

Appendix 1: AGU Reference Standards

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Appendix 2: Documentation to be Delivered with Each Lot of ACU

- CoC – certificate of compliance with cGMP
- COA – certificate of analysis
- TSE Statement – one-time; with updates as required
- Copies of executed batch records and any planned deviations
 - o Associated QC data and results
- Cleaning/changeover verification information from previous campaign to AGU
 - o Redacted cleaning verification form, numerical data, and documented acceptance by AVECIA QA
- Copies of all deviations/variations related to manufacturing, in-process testing, raw materials testing, and facility monitoring.
- Copies of all OOS investigations or other quality incidents related to the batch
- Copies of all change controls related to the batch
- EM (environmental monitoring) data and interpretations for manufacturing processing rooms across the period of production (if applicable)

END OF DOCUMENT

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the “*Agreement*”) dated July 27, 2016 (the “*Effective Date*”), is between WEST PHARMACEUTICAL SERVICES, INC., a Pennsylvania corporation (“*West*”), and DYNAX TECHNOLOGIES CORPORATION, a Delaware corporation (“*Customer*”).

Customer desires to purchase from West, and West desires to sell to Customer, the items listed on Exhibit A hereto (the “*Products*”) on the terms and subject to the conditions set forth below. Accordingly, the parties hereto, intending to be legally bound, agree as follows:

1. Agreement to Sell and Purchase Products.

West will sell to Customer, and Customer will purchase from West, one hundred percent (100%) of Customer’s requirements for the Products (and Customer will not purchase goods manufactured by third parties that are substantially similar to the Products) in accordance with the terms and subject to the conditions of this Agreement, including the Exhibits hereto. Notwithstanding anything to the contrary, (i) all orders of Products may be submitted to West by Baxter Pharmaceutical Solutions LLC or its affiliates (collectively, “*Baxter*”) on behalf of Customer, and all orders of Products may be delivered to a Baxter location if so specified in the applicable purchase order, and (ii) all Products may be inspected and used by Baxter on behalf of Customer under this Agreement.

1.1 In the event that West is unable to supply Product to Customer in accordance with the terms of this Agreement (including if West provides a proposed delivery date in an order acknowledgment that is greater than [*] months, as described in Section 4.1), Customer’s purchase obligation in Section 1.1 above shall be waived until such time as West can recommence the supply of such Product; provided, that Customer will permit West to manufacture any such Products at non-affected West manufacturing plants, subject to such alternate plants’ satisfying the quality and regulatory obligations imposed herein on the affected West manufacturing plants.

2. **Term.** This Agreement will commence on the Effective Date and, unless terminated earlier as provided herein, will continue in effect until the fifth anniversary thereof (the “*Term*”); the Term shall automatically extend by successive two year periods thereafter on the same terms unless either party provides notice to the contrary to the other party not less than two years prior to the end of the then-current Term.

3. **Intentionally omitted.**

4. Purchase Orders and Forecasts.

4.1 Firm orders for Product shall be placed by Customer in writing. All orders shall specify quantities ordered, and delivery and shipping instructions and such other information as West may reasonably request in order to allow West to fill the order. The lead time on orders will be established by West in writing at time of order acknowledgement, as described below. Within ten (10) days of West’s receipt of an order from Customer, West shall deliver to Customer a written order acknowledgment that, among other things, confirms the (i) quantity of Products that West will provide to Customer, and (ii) date of delivery by West of such ordered Products to Customer. Notwithstanding West’s acceptance of any purchase order, if the date of delivery provided by West exceeds [*] months from the date of the purchase order, then Customer has the right to purchase products similar to the Products (in the same

1.

quantity specified in the applicable purchase order submitted to West) from another vendor (unless another West site, whose site and Products are qualified by Customer, can provide the Products in less than or equal to [*] months). West shall deliver ordered Products to Customer by the delivery date specified in the applicable order acknowledgement, subject to the 3 day delivery window set forth in Section 6.

4.2 To facilitate timely delivery of Product, West and Customer shall cooperate fully in estimating and scheduling the first order of commercial quantities of Product to be placed by Customer. Prior to the end of each calendar year during the Term (as defined herein), Customer shall provide West with Customer's estimate of its quarterly requirements of Product for the next calendar year. Product shall be delivered only in response to firm Customer purchase orders indicating exact quantities ordered and requested delivery dates.

5. Delivery and Payment Terms.

5.1 Payment terms are net thirty (30) days from date of receipt of delivery and invoice. West may charge Customer a late payment fee equal to one and one-half percent (1.5%) of any undisputed and unpaid amounts each month (or part thereof) such payment is late.

5.2 Pro rata payments will become due as shipments are made, including multiple shipments on a single order. If shipments are delayed by Customer for any reason, payments will become due from the date on which West is prepared to make shipment and storage shall be at Customer's risk and expense as provided in Section 8 hereof. If manufacture is delayed by Customer for any reason, a partial payment based upon the proportion of the order completed will become due from the date on which West is notified of the delay.

5.3 Product prices from West facilities located in the United States do not include pallet charges, which are separately chargeable at then-current fees. Pallet sizes and their associated fees (applicable during 2016) are as follows:

SUMMARY – PALLETS / MISC. PACKAGING	[*] PRICE/EA
40 X 48 PLASTIC PALLET (Upped / Non-lipped)	[*]
31.6 X 47.26 inches EURO PALLET-KEARNEY	[*]
48 x 44 - 4 WAY HEAT TREATED PALLET	[*]
48 x 44 - 2 WAY HEAT TREATED PALLET	[*]
29 x 29 - 2 WAY WING HEAT TREATED PALLET	[*]
48 x 40 - 4 WAY HEAT TREATED GMA	[*]
62 x 40 - 4 WAY HEAT TREATED PALLET	[*]
43 x 48 - 4 WAY HEAT TREATED PALLET	[*]
8 X 8 x 10" PALLET CONE (Including Yellow)	[*]
PALLET SLEEVE	[*]

Pallet Prices above include add'l cost for cornerboards (mandatory requirement)

6. Delivery: Risk of Loss. All sales are EXW Origin (Incoterms 2010). Shipping dates are estimates only, which are not guaranteed and are based upon prompt receipt from Customer of all necessary shipping and other information. West shall endeavor to effect deliveries within +/-3 days of the acknowledged delivery date. Delivery of ten percent (10%) more or less than the quantity specified shall

2.

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

constitute fulfillment of the order. West reserves the right to make delivery in installments within the 3 day delivery window of the delivery date set forth in the applicable order acknowledgment, unless Customer consents to receiving certain specified installments outside of such period, which installments shall be separately invoiced and paid for by Customer when due per invoice, without regard to subsequent deliveries.

7. Inspection. Customer will examine each shipment upon its arrival at the specified destination and will promptly notify West of any shortage, loss or damage apparent under reasonable visual examination. Failure by Customer to notify West within sixty (60) days of the date of arrival at the specified destination will constitute a waiver of all claims for such shortage, loss, or damage. If Customer discovers that a Product has a latent defect, then Customer shall notify West within sixty (60) days of Customer's discovery of such latent defect. Claims for loss or damage to Product in transit by common carrier must be made to the carrier and not to West.

8. Storage. If Products are not shipped within thirty (30) days after notification has been made to Customer that they are ready for shipping for any reason beyond West's control, including Customer's failure to give shipping instructions, West may store the Products at Customer's risk and expense in a warehouse or upon West's premises, and Customer will promptly pay all handling, transportation and storage expenses at the prevailing commercial rates following West's submission of invoices for such amounts.

9. Representations, Warranties and Covenants of West. West represents, warrants and covenants to Customer as follows:

9.1 West has, will maintain and will comply with, all permits, licenses and other authorizations that are required under all federal, state and local laws, rules and regulations applicable to West's obligations under this Agreement.

9.2 West and any West personnel performing hereunder have not been, and will not use the services of any person or entity in any capacity in the performance of this Agreement, currently or ever debarred under 21 U.S.C. §335a or convicted of a felony for conduct relating to the regulation or handling of any drug product. West shall notify Customer immediately if, during the term of this Agreement, West or any West personnel come under investigation by the U.S. Food & Drug Administration (the "**FDA**") for debarment or disqualification or are debarred or disqualified. West shall notify Customer within one business day if the FDA or any other regulatory authority requests permission to or does inspect West's records in connection with the services and Products provided under this Agreement, and West will deliver to Customer promptly all materials, correspondence, statements, forms, and records that West receives, obtains, or generates pursuant to any such inspection or communication with regulatory authorities. West agrees that during an inspection by the FDA or other regulatory authority concerning the Products, it will not disclose information and materials that are not required to be disclosed to such agency without the prior consent of Customer, which consent shall not be unreasonably withheld.

9.3 To the best of West's knowledge, the Products and West's manufacture of Products in the performance of this Agreement will not infringe upon the intellectual property or other rights of any third party.

9.4 Title to all Products provided to Customer hereunder shall pass to Customer free and clear of any security interest, lien or other encumbrance, excepting those arising by or through Customer.

3.

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West shall comply with the terms and conditions of that certain Supplier Quality Agreement effective as of January 15, 2015, between Customer and West, as amended, supplemented or replaced from time to time, applicable to the manufacture of the Products and attached hereto as **Exhibit B**.

10. Insurance. Until payment in full of the purchase price, Customer shall maintain insurance covering all Products sold by West to Customer in such amounts and against such risks as is customary by companies engaged in the same or similar business and similarly located, and shall, upon West's request, furnish evidence of such insurance satisfactory to West.

11. Order Cancellations. Orders are not subject to cancellation, change, reduction in amount or suspension of deliveries, except with West's written consent and subject to West's associated, documented and reasonable fees, which consent shall not be unreasonably withheld, delayed or conditioned and which fees shall be agreed upon by the parties before any modification to such order. Customer may elect to cancel a particular delivery of Product if West fails to deliver the Product as agreed or upon West's notice to Customer of West's inability to meet agreed-upon lead times; provided, that the foregoing shall not apply during a force majeure event.

12. Force Majeure. Neither party assumes responsibility for any loss or damage occurring by reason of any delay or inability to perform its obligations hereunder or deliver caused by fires, strikes, accident, delays of common carriers or from any other cause which is unavoidable or beyond the applicable party's reasonable control and without the fault or negligence of such party. Should any of such events occur, the applicable party shall give prompt notice to the other party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible. Notwithstanding the foregoing, West, at its option, may cancel Customer's order with respect to any undelivered goods or extend the delivery date for a period equal to the time lost because of such delay. If West elects to so cancel the order due to a force majeure event, West will be released from all liability for failure to deliver Products subject to the order in question. If shipping or progress of the work is delayed or interrupted by Customer directly or indirectly, Customer will pay West for all resulting additional charges. If West is not able to fulfill an order by Customer of Products, in whole or in part, as a result of a force majeure event, then during and after such force majeure event West shall not treat Customer less favorably in supplying Products to Customer as compared to West supplying products to West's other customers.

13. Warranties; Remedies and Limitations of Liability.

13.1 Product Warranty. West represents to Customer that as of the date of shipment, the Products shall conform to any specifications specifically agreed to in writing by West and Customer; provided, that in the absence of such mutually agreed-to specifications for any Product, West represents to Customer that as of the date of shipment, that Product shall conform the applicable West global master specification (collectively, the "**Product Specifications**"). Customer acknowledges and agrees that all Products are sold only on the basis that it is the sole responsibility and duty of Customer to evaluate and test the Products, assure that the Products are fit for the uses and purposes for which Customer intends to use them, and are compatible with Customer's particular product and its processing and packaging methods. Customer assumes all risks whatsoever as to the result of the use of the Products, whether used singly or in combination with other goods or substances. **THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** West's warranty runs solely to Customer.

4.

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13.2 Remedies of Seller. West will replace any of the Products shown to be nonconforming to the Product Specifications or, at Customer's option, provide Customer with a credit for the amount paid for the nonconforming Products, provided Customer provides timely notification, as per Section 7. Purportedly nonconforming Products shall not be returned without West's prior written approval. West may request that Customer destroy nonconforming Products, such destruction to be certified in writing by an appropriate officer of Customer. THE PROVISIONS OF THIS SECTION 13 SET FORTH CUSTOMER'S EXCLUSIVE REMEDY AND WEST'S SOLE LIABILITY ON ANY CLAIM RELATING TO PRODUCT DEFECT OR NONCONFORMANCE, WHETHER IN TORT, CONTRACT, OR WARRANTY ARISING OUT OF THIS CONTRACT. IN NO EVENT SHALL WEST BE LIABLE FOR INDEMNIFICATION OF CUSTOMER ON ACCOUNT OF ANY SUCH CLAIM ASSERTED AGAINST CUSTOMER OR FOR ANY OTHER FURTHER DAMAGE, COST, EXPENSE OR LIABILITY OF ANY KIND WHATSOEVER, WHETHER DIRECT OR INDIRECT, INCLUDING WITHOUT LIMITATION, INCIDENTAL, PUNITIVE, EXEMPLARY AND/OR CONSEQUENTIAL DAMAGES TO CUSTOMER OR ITS CUSTOMERS ARISING FROM ANY DEFECT IN MATERIALS OR WORKMANSHIP OR DELAY IN PERFORMANCE OR DELIVERY, even if West has been advised of the possibility of such damages.

13.3 Limitations of Liability. Customer agrees that no claims arising out of the performance or non-performance of any of the terms and conditions of this Agreement for the sale of Product shall be valid against West unless commenced within [*] of delivery of the particular Product. In no event shall West's aggregate liability hereunder exceed the amount charged by West for any applicable nonconforming Product. Nothing herein contained shall be construed to limit the time for commencement of an action by West to recover all or any part of the purchase price.

14. Price and Price Adjustments. Initial Product prices are set forth on **Exhibit A** hereto, which shall be firm through [*]. Thereafter, the prices set forth in this Agreement shall be adjusted by the percentage increase in the United States Producer Price Index (the "**PPI Index**") for "**Processed Materials (Other)**" issued by the U.S. Bureau of Labor Statistics (Ref. Series ID WPSID69111). Such adjustments shall be made annually on each subsequent anniversary of this Agreement during the Term by comparing the average change in the PPI Index each month over the twelve month period ending the preceding September 30 against the average change in the PPI Index each month over the immediately preceding twelve month period.

15. Drawings and Tooling.

15.1 All specifications, Product Specifications, drawings, design, data, information, ideas, methods, patterns, and/or inventions made, conceived, developed, or acquired by West in connection with procuring and/or executing Customer's order will vest in and inure to West's sole benefit notwithstanding any charges therefor which may have been or may be imposed by West.

15.2 Tooling (including molds and dies) designed or fabricated by West will not be returned to Customer under any circumstances. Tooling supplied by Customer will be returned only with West's prior consent and will be shipped EXW (INCOTERMS 2010) West's plant and subject to normal packing charges. All tooling shall be subject to West's tooling program in effect as of the date of most recent sale of Products hereunder and associated fees.

16. Confidentiality. As used in this Agreement, the term "**Confidential Information**" means (i) information, specifications, know-how, materials, data, and other communications relating to the supply of Products which are disclosed or provided by one party to the other (including all reports and data created as a result thereof), whether in oral, written, or in any electronic or other tangible form and

5.

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(ii) any information from whatever source supplied to or obtained by Customer concerning the trade secrets, customer business associations, transactions, financial arrangements and technical or commercial affairs of West, whether or not such information is related to the supply of Products. Confidential Information includes, without limitation, all portions of analyses, studies and other documents containing any of the foregoing.

16.1 Each party will keep all of the other party's Confidential Information confidential and will not use such Confidential Information for its own purposes or for the benefit of any third person. Without the prior written consent of the other party, neither party will analyze, have analyzed, or otherwise attempt to determine the composition or structure of any samples, nor disclose any of the other party's Confidential Information to any third party other than its employees strictly on a need-to-know basis or to its attorneys, accountants or consultants who are bound by confidentiality obligations no less stringent than the confidentiality obligations hereunder.

16.2 All written disclosures of information considered to be Confidential Information by the disclosing party shall bear the notation "**Confidential**" or a similar notation. All non-written disclosures of Confidential Information shall be confirmed by the disclosing party in writing as being confidential within thirty (30) days following the non-written disclosure, unless a reasonable person would ordinarily assume such non-written disclosure to be of a confidential nature. The written confirmation shall identify the particular Confidential Information, state that it is considered confidential, and shall be addressed to the persons who received such non-written disclosures.

16.3 Each employee or agent of the recipient party who receives any non-written disclosures of the other party's Confidential Information shall first be informed that the Confidential Information is confidential; provided, that no such disclosure shall be permitted unless such person has first executed a written agreement containing a confidentiality obligation no less stringent than this Section. Each party shall ensure that the other party's Confidential Information is not used or disclosed in any manner except to perform the recipient party's obligations hereunder and as permitted by this Agreement and shall indemnify the other for any breach of this Agreement by itself, its employees, and any other party that receives, has access to, discloses, or otherwise comes into contact with such Confidential Information through the action or inaction of said party hereto.

16.4 All Confidential Information disclosed by the disclosing party shall remain the property of the disclosing party, except for analyses, studies, or other documents prepared for the benefit of the recipient party. Upon the written request of the disclosing party: (a) all tangible Confidential Information (including all copies thereof), except analyses, studies, and other documents prepared for the benefit of the recipient party, shall be promptly returned to the disclosing party; (b) to the extent any analyses, studies, and other documents prepared for the benefit of the recipient party (including all copies thereof) contain Confidential Information, such Confidential Information shall be redacted or deleted therefrom, or such analyses, studies, and other documents shall be destroyed; and, (c) to the extent the receiving party has otherwise incorporated or used Confidential Information in any other manner, such Confidential Information shall be deleted, redacted, or destroyed in its entirety.

16.5 The obligations of confidentiality and non-use set forth in this Section shall not apply to any portion of the Confidential Information which:

(a) legitimately and through no other breach of any confidentiality obligation is or becomes available to the general public other than through the act or default of the recipient or its agents;

6.

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(b) is obtained by the recipient party from a third party who is rightfully in possession of the Confidential Information and does not violate any obligation of confidentiality or non-use by disclosing such Confidential Information;

(c) is in the recipient party's possession and is not subject to any confidentiality obligation prior to disclosure by the disclosing party;

(d) is independently developed by the recipient party without use of or access to the Confidential Information; or

(e) is disclosed by the recipient party pursuant to a requirement of law, provided that the recipient party has complied with the provisions of paragraph 15.7 below.

16.6 If the recipient of Confidential Information is requested or required by any legal process (such as deposition, interrogatories, requests for information, documents or admissions, subpoenas, or the like) to disclose any Confidential Information, the recipient party will promptly notify the disclosing party; however, the recipient party shall not disclose Confidential Information unless required to do so. The disclosing party may seek an appropriate protective order and/or waive the recipient party's obligation to comply with this Agreement. The recipient party will reasonably cooperate with all efforts to obtain any such order or other remedy at the disclosing party's expense. If no protective order is obtained and the recipient party has not received a waiver hereunder before one (1) business day prior to the time the recipient party must disclose Confidential Information or else stand liable for contempt or suffer other sanction or penalty, the recipient party may disclose the applicable Confidential Information to the minimum extent legally required; provided, the recipient party shall use commercially reasonable efforts to have such disclosed Confidential Information treated as confidential.

16.7 Specific information disclosed as part of Confidential Information shall not be considered available to the general public, in the public domain, or in the prior possession of the recipient party merely because it is embraced by more general information available to the general public or in the prior possession of the recipient.

16.8 The parties recognize and acknowledge the competitive value and confidential nature of the other's Confidential Information and the irreparable damage that could result if Confidential information is disclosed in violation of this Agreement. Either party may unilaterally institute appropriate proceedings to enforce its rights hereunder. The parties acknowledge and agree that money damages would be an insufficient remedy for any violation of this Section 16 and, accordingly, either party shall be entitled, in addition to any monetary damages, to specific performance and injunctive relief as remedies for any violation by the other. These remedies shall not be exclusive but shall be in addition to all other remedies available at law or in equity.

16.9 The obligations as to confidentiality and non-use contained in this Section shall survive for five (5) years from any termination of this Agreement.

17. Default and Termination.

17.1 Either party has the right to terminate this Agreement upon material breach by the other party upon thirty (30) days' notice if such breach is not cured within such 30-day period. Such notice will specify in reasonable detail the material breach that is the basis upon which this Agreement is to be terminated. If by its nature such breach cannot be cured within such 30-day period and the breaching party is proceeding diligently to effect a cure of such breach, then this Agreement may not be terminated

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for an additional 30 days or until such time as the breaching party ceases to effect a cure, whichever is shorter.

17.2 This Agreement may be terminated by either party on immediate written notice in the event that the other party becomes insolvent, bankrupt, makes an assignment for the benefit of creditors, or otherwise becomes subject to a plan of reorganization.

17.3 Sections 5, 12, 15 and 16 shall survive any termination of this Agreement.

18. Compliance with Laws. West shall comply with all applicable State and federal laws and regulations in the performance of its obligations hereunder, including without limitation the manufacture and delivery of Product, including but not limited to the US Food, Drug and Cosmetic Act.

19. Miscellaneous.

19.1 Limitation of End Usage. Notwithstanding any other provision of this Agreement, Customer acknowledges and agrees that Products shall be used for the production of pre-filled syringes of Customer's HEPLISAV-B™ product and not any other end usage without the prior written consent of West, which West may withhold in its sole and absolute discretion. Customer shall not re-sell or further distribute Products except as they are incorporated into Customer's products as contemplated herein.

19.2 Conflicting Documents. Terms or conditions contained in any purchase orders, invoices, sales receipts, shipping documents, forms, billing documents or other similar documents issued by either party hereto to the other shall be without force or effect, and no amendment or alteration to this Agreement shall be effective unless it is in writing and executed by both parties.

19.3 Assignment. Except in the event of a purchase, merger, or consolidation of all, or substantially all, of the assets of a party hereto, neither this Agreement nor any of the rights hereunder may be assigned by either party hereto except with the prior written consent of the other party, and any purported assignment to the contrary shall be void.

19.4 Notices. All notices, requests, consents, and other communications required or permitted under this Agreement shall be in writing and shall be hand-delivered (with delivery effective on the date of delivery), mailed by postage prepaid registered or certified mail, return receipt requested (with delivery effective on the date said receipt is acknowledged), sent by a nationally-recognized guaranteed overnight delivery service (with delivery effective on the date of delivery), or sent by facsimile transmission (with delivery effective on the date of transmission), and addressed to:

If to Customer:

Dynavax Technologies Corporation
2929 Seventh Street, Suite 100
Berkeley, CA 94710
Attn: Vice President, Operations and Quality
Telecopier Number: (510) 848-1327

with a copy to:

Dynavax Technologies Corporation
2929 Seventh Street, Suite 100

8.

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Berkeley, CA 94710
Attn: General Counsel
Telecopier Number: (510) 848-1327

If to West:

West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, Pennsylvania 19341
Attn: VP & GM, Global Biologics

with a copy to:

West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, Pennsylvania 19341
Attn: General Counsel

or to such other place and with such copies as either party may designate by notice to the other party in the manner prescribed above.

19.5 Taxes. All tax liability directly or indirectly arising out of this Agreement (including, without limitation, all VAT, occupational, sales, use, gross income or other taxes, and import and export duties levied by any governmental body), except federal and State income and employment taxes imposed upon West, shall be paid by Customer either directly or by reimbursement to West, as appropriate.

19.6 Applicable Law. This Agreement shall be construed and interpreted in accordance with the laws of the State of Delaware, regardless of the laws governing the principles of conflicts of laws applicable thereto.

19.7 Severability. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

19.8 Waiver. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by a party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

19.9 Independent Contractor Status. The relationship of West and Customer established by this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed to constitute West or Customer as a partner, agent, or joint venturer with the other party or as a participant in a joint or common undertaking with the other party.

19.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original but together shall constitute a single Agreement.

19.11 Headings. The paragraph headings herein are for convenience only and shall not affect the meaning or interpretation of this Agreement.

9.

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19.12 **Entire Agreement.** This Agreement and the Exhibits attached hereto, which are incorporated herein by reference, constitute the entire agreement between the parties concerning the subject matter contained in this Agreement and supersedes all written or oral prior agreements or understandings with respect thereto. No course of dealing, usage of trade or course of performance will be relevant to explain or supplement any of these terms and conditions. No variation or modification of any of the terms or exhibits of this Agreement or any waiver of the terms of provisions hereof shall be valid unless in writing and signed by an authorized representative of each party.

10.

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IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute this Agreement.

DYNAVAX TECHNOLOGIES CORPORATION

WEST PHARMACEUTICAL SERVICES, INC.

By: /s/ Kenneth Wiehe
Name: Kenneth Wiehe
Title: Sr. Director, Supply Chain

By: /s/ William Federici
Name: William Federici
Title: Chief Financial Officer

11.

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EXHIBIT A

PRICING EXHIBIT

PRICE MASTER EFFECTIVE THRU DECEMBER 31, 2017

C. ITEM #	ITEM #	ITEM DESCRIPTION	QTY (000)	PRICE	QTY (000)	PRICE	QTY (000)
85	10149685	ART 2345 4432/50GY B2-40 WESTARRU/SP01	[*]	[*]	[*]	[*]	[*]

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SUPPLIER QUALITY AGREEMENT

Between

Dynavax Technologies Corporation

And

West Pharmaceutical Services, Inc.

**Supply of
Stopper [*]**

1. INTRODUCTION

In an effort to improve customer relations and to support continuous improvement as a supplier between West Pharmaceutical Services, Inc. ("**West**") and Dynavax Technologies Corporation ("**Dynavax**"), this Quality Agreement (this "**Agreement**") has been developed to define the conditions to be fulfilled by West as a molded component and packaging supplier to Dynavax. This Agreement will also provide assurance that West will comply with appropriate Dynavax quality assurance requirements. This Agreement shall be executed by authorized representatives of Dynavax and West. The criteria listed below are considered conditions of business and critical success parameters, which are predicates to a mutually beneficial supply relationship.

2. Amendments to Agreement

This Quality Agreement may be amended as needed by the written approval of both Parties. The Parties shall amend those terms of the Agreement as necessary to meet any regulatory requirement of applicable regulatory agencies.

If amendment(s) to the Agreement are proposed to be made, Dynavax and West will circulate the proposed revised document to the Quality Assurance at Dynavax and the Quality Assurance at West for review and internal approval as well as such other review and approval as West and Dynavax may determine necessary or advisable. Both Parties, in writing, must approve such amendment.

Each Party may change its own Contact and Responsibility by written letter delivered to the other Party.

3. Other Agreements

This Quality Agreement shall be in addition to any other agreements between the Parties governing the obligations of confidentiality and non-disclosure as to confidential information. If there are any inconsistencies between the terms of this Quality Agreement and these other agreements, the provisions of Quality agreement shall control for the quality related items, the supply agreement will control for all business, financial and all other matters.

4. Term of Agreement

This Agreement shall commence on the Effective Date and shall remain in effect unless terminated by a Party with six (6) months' prior written notice to the other Party, or expiration of supply agreement except for provisions which, by their nature, are intended to survive.

13.

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5. Assignment

Neither Party shall have the right to assign any or all of its rights or obligations under this Agreement without the other Party's prior written consent which shall not be unreasonably withheld. Notwithstanding the foregoing, such other Party's consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of the assets of the first Party or the subject matter of this Agreement to another Party, provided, however that written notice of such transaction is provided to the other Party.

6. Choice of Law: Jurisdiction

This Agreement shall be construed and the relationship between the Parties determined in accordance with the laws in the State of Delaware, United States of America, without regard to the conflicts of law principals thereof. Any and all disputes between the Parties arising out of or related to this Agreement shall be heard in the state and federal courts located in the State of Delaware and the parties hereby consent and submit to the jurisdiction of such courts.

7. Survival Clause

Except as otherwise agreed in writing by the Parties, all regulatory obligations contained herein required of Dynavax and West shall survive termination of this Agreement with respect to the Products sold by West to Dynavax prior to such termination for the purpose of making End Products.

8. Quality System

West shall establish, document, and maintain an internal quality assessment and measurement system as a means of verifying that the Stoppers [*] sold by West to Dynavax (the "**Product**") conform to specified requirements. West's quality system shall take into consideration the following activities and conditions, as appropriate, in meeting the specified requirements for identified products and related manufacturing processes:

Facilities

West shall provide and maintain facilities to manufacture, pack, store, test and distribute Products conforming to the specified requirements. The facilities and operating environments will not adversely affect the quality of the Product.

West will produce the Product at the Jersey Shore, PA site, which has its primary location at 347 Oliver Street, Jersey Shore, PA 17740. The floor plan of the manufacturing area and corresponding room classification is available for review during annual audit of the facility.

Equipment

West shall provide and maintain suitable production and quality control equipment that may be needed to achieve full compliance of Products with the applicable regulatory requirements.

Personnel

West shall provide adequate resources, including the assignment of competent and trained personnel, in order to enable it to manufacture the requested quantities of Product.

14.

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Materials

West shall establish, monitor, and use a quality system that will verify that incoming raw materials conform to West specifications.

The ISO 9001 and ISO 14000 series, as applicable, are guides to the development, implementation, and monitoring of such a quality system. This includes ISO 15378: Quality Management systems-Primary packaging materials for medicinal products-Particular requirements for the application of ISO 9001:2008, in accordance with cGMP.

West will give special attention to the efficacy of all procedures in order to verify that Product identity and labeling, shipping configuration requirements, and purity of materials supplied to Dynavax (e.g. contamination or mix-up prevention) are in accordance with the Product specifications.

9. Design and Development, Regulatory Support

West will establish and use a system of Product and process design and development in order to verify that Product meet their specified requirements.

West commits to provide a timely DMF submission to the U.S. FDA and the Canadian Health Protectorate, if required, and will provide an appropriate letter of authorization to reference the applicable DMF upon request.

West supports Dynavax with applicable documentation for their submission in Europe.

When requested, West will supply other data (e.g. CONEG compliance, European directive 94/62/EC) required by regulatory agencies to support regulatory filing.

West will adhere to all relevant regulatory requirements (e.g. DMF-updates) and send Dynavax revisions of any controlled documents previously supplied.

10. Process and Product Quality Documentation

West agrees to document:

- All process steps that affect Product quality.
- All quality control activities needed to demonstrate conformance to specified requirements.
- All activities demonstrating the effective operation of the quality system.

West agrees to assign an internal unique lot number to any discrete quantity of Product produced in such a way that it can be considered homogeneous and having the same quality characteristics. If requested, the forma and rationale of the internal numbering system is to be communicated to Dynavax. In cases where the material is made following a continuous process, West agrees to refer to a set of test results being most representatives for the period the Product provided is produced.

West will retain all documents with lot specific information (e.g. process run, equipment used, raw materials used, line clearance certification, environmental control data (where applicable), utility monitoring results, release testing results, etc.) for a minimum of seven (7) years from date of

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manufacturing. In addition, West will retain a sufficient identified sample quantity for retesting, for a minimum period corresponding to the Use-by-Date.

11. Documentation Retrieval System

West recognizes that in certain circumstances Dynavax may have special documentation needs. West will make ourselves available to support this based upon adequate prior notice. West will also attempt to support any emergency situation that may arise based upon the urgency established by the authorities. West will endeavor to complete all such activities on a timely basis, starting when Dynavax provides West with all of the relevant information needed to initiate such an activity.

West agrees to make all applicable process and QC/QA documents relating to all supplied Product lots, available for review on reasonable notice during normal business hours.

12. Manufacturing Process and Site Specificity

West will not change the materials (composition and characteristics) of Product as specified in the applicable specification documents or change the process or critical process parameters without first notifying Dynavax, subject to West's customer change notification policy (attached hereto as Attachment - 3).

In the absence of an agreed to customer-specific specification, West will utilize the latest revision of West documents for:

- Global Specification for Westar®RU Elastomers (Attachment 2)

Dynavax may re-qualify Product and re-audit the site in case of any significant change.

13. Packaging:

For Part # [*] — Special Packaging:

- PRIMARY BAG: 5,000 PCS PER STERILIZABLE BAG (XD3 Enhanced) HEAT SEALED WITH LABEL
- SECONDARY BAG: STERILIZABLE BAG HEAT SEALED WITH LABEL
- TERTIARY BAG: Polyethylene bag — PARTIAL VACUUM AND HEAT SEALED
- 10,000 PCS PACKAGED IN PLASTIC CARTON

14. Disposition of Non-conforming Product and Continuity of Supply

In case of non-conforming Product, West agrees to perform a full investigation including root cause identification and corrective and preventative actions and supply a complete response to Dynavax within a 30 days from receipt of the initial notification with all information necessary for the investigation. Appropriate samples and information must be supplied by Dynavax in order to allow West to conduct an adequate investigation and should be presented to West prior to the commencement of the Product Discrepancy Report (PDR).

Dynavax will be contacted on the final disposition of the material and a Return Goods Authorization Number (RGA) will be issued by West should product return be necessary.

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Reasonable efforts will be made by West in an effort to replace the material in a timely fashion.

15. Technical Assistance

West will investigate any claim or notice presented pertaining to the Product supplied. In addition, West will address within a reasonable period of time all technical issues brought to its attention. West will periodically update Dynavax regarding its investigation of ongoing technical reviews. West will assign appropriate-level technical service staff to address any Product nonconformities and/or process deficiencies.

16. Supplier Quality Audits and Frequency

Dynavax may perform quality audits at West sites annually for a maximum of one day and on a mutually approved date. West will permit Dynavax to conduct “For Cause” audits to address significant product quality of safety problems as discovered through Product failure or recurrent complaints. All quality audits shall be scheduled in advance on reasonable notice and take place during normal business hours, unless circumstances warrant otherwise.

17. Quality Responsibilities

1	Compliance Requirements	Dynavax	West
1.01	Follow procedures and/or documented training regarding its internal quality system procedures.		X
1.02	Use standards or guidances, such as ISO, EU GMPs, and cGMP as references to the extent applicable to Products.		X
1.03	Manufacture Product in adherence to the WEST Specifications.		X
1.04	Manufacture the Product in adherence to the applicable Technical Document or Drug Master File.		X
1.05	Operate in compliance with applicable environmental, occupational health and safety laws and regulations.		X
1.06	Notify other Party of requests for information from regulatory agencies which are related to Dynavax’s application and the Product sold by West to Dynavax.	X	X
1.07	Maintain a quality unit that fulfills both quality assurance and quality control functions.	X	X
1.08	Involve its quality unit in all quality related matters and have them review and approve all quality related documents such as Change notification, Regulatory audit observation/response, Recall notification, adverse event, post release discrepancy related to Dynavax application with Product as applicable.	X	X

17.

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2	Right to Audit		
2.01	Have the right to audit WEST's facilities and systems, as they relate to the manufacture of Product, at annually agreed upon times, subject to appropriate confidentiality agreements, agendas and other customary WEST policies and restrictions.	X	
2.02	During audits properly conducted as described above have right to review of documents to assure continued adherence to the Specifications, and other applicable requirements agreed by the Parties related to Product.	X	
2.03	Issue WEST a confidential audit report summarizing audit observations, this audit report shall not be disclosed by Dynavax to any third party without the prior express written consent of WEST and shall be used by Dynavax solely in connection with the supply of Product by WEST to Dynavax.	X	
2.04	Issue responses to all requests for action contained in the above delivered audit report in writing to Dynavax Quality Assurance within 30 days from receipt of audit report.		X
3	Inspections and Exchanges		
3.01	Notify Dynavax of any significant issue within 2 working days of a Regulatory Authority observation if it relates to a WEST facility or to the Product but only to the extent each of them relates to Dynavax's End Product.		
3.02	Provide Dynavax, by facsimile a redacted copy or electronically, within 3 working days of notification of correspondence from a Regulatory Authority if it relates to both Product and Dynavax's application.		X
3.03	Provide a copy of the Regulatory inspection report, or regulatory compliance observation and response to the extent it relates to both Product and Dynavax's application, edited to exclude WEST proprietary information, and allow Dynavax to comment on WEST's written response (if any) relative to such above matters.		X
4	Complaints		
4.01	Have written procedures in place to document and investigate all quality related complaints. Assist in investigations as requested by Dynavax for complaints associated with Products and Dynavax end product.	X	X

18.

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4.02	Retain complaint investigation records in respect of Products and evaluate trends and severity. Implement corrective actions with respect thereto as each Party determines to be necessary for its product.	X	X
4.03	Provide appropriate information related to complaints (included, if available, complaint samples) within one week.	X	
5	Animal Derived Materials		
5.01	When requested by Dynavax in writing, WEST will supply relevant information/statement to Dynavax on animal derived material content in Product necessary for a TSE/BSE risk assessment.		X
6	Validation/Qualification		
6.01	Have a written master validation/qualification plan for the manufacturing process, cleaning procedures, analytical procedures and equipment, in process control tests and computerized systems approved by the quality unit in respect of Products.		X
6.02	Maintain validation/qualification documentation approved by the quality unit, including protocols, and reports in respect of Products.		X
6.03	Qualify as necessary all critical systems and equipment used for the manufacture and control of Product (Installation Qualification (IQ), Operational Qualification (OQ), and/or Performance Qualification (PQ)).		
6.04	Evaluate, through appropriate stability studies and otherwise, the appropriateness of the Product for its use with its compounds and other materials comprising part of Dynavax's processes, components and products, and for validating the Product with respect to all such materials, compounds and processes	X	
7	Documentation and Records		
7.01	Have a system to control quality documents with respect to Products and establish retention periods of such documents.	X	X
7.02	Have written procedures for the review, approval, and retention of production documentation with respect to Products.	X	X
7.03	Maintain a document control system for (1) WEST Specifications, (2) raw materials and (3) other materials defined by West, in each case that affects Product quality.		
7.04	Provide a Certificate of Compliance (COC) and CofA for each lot of Product shipped to Dynavax with results of particles, B2-level, biological indicators and Bacterial endotoxin.		X
8	Regulatory Submissions		

19.

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8.01	Notify WEST if WEST or the Product will be named in any governmental filing submitted by Dynavax, prior to such filing being made.	X	
8.02	Maintain required Drug Master File and Regulatory applications in accordance with the regulations of the applicable regulatory authority.		X
8.03	Subject to WEST appropriate confidentiality protection, provide Letters of Authorization (LOA) to Dynavax, upon written request by Dynavax, to permit cross-reference to WEST's Product Drug Master File for U.S., Canada and Australia and EU Technical Document for inclusion in Dynavax's Drug Product application.		X
9	Change Control		
9.01	Have established written procedures for control of changes impacting the Product including but not limited to manufacturing components or process, Product specifications, test methods, suppliers, and subcontractors. Include in procedures the process and criteria for customer notification and approval.		X
9.02	Follow such written procedures so as to notify Dynavax of intent to make changes that impact the identity, Specification, regulatory status, or validation prior to implementation to allow time for Dynavax to assess the change, all in the manner and to the extent provided in the procedures described in Section 9.01 and per Attachment 3. Major changes as per West definition in Attachment 3 require prior approval from Dynavax Technologies prior to implementation. This approval must not be unreasonably withheld by Dynavax.	X	X
9.03	Issue to Dynavax a written evaluation of the notified change to determine the impact on Product quality and validation in the manner and to the extent provided in the procedures described in Section 9.01.		X
9.04	Have changes to WEST Specifications reviewed and approved by the appropriate WEST's organizational and quality unit.		X
10	Deviations		
10.01	Have procedures for managing deviations that occur during the manufacture and testing of the Product.		X
10.02	Assist Dynavax to complete material investigations for deviations from WEST Specifications found in Product at receipt (i.e. corrective actions)		X

20.

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10.03	Notify Dynavax of major or critical deviation which were discovered after the release of the batch associated with already shipped Product batch within 2 working days after discovery.		X
11	Reprocessing		
11.01	No rework out of validated process of the Product is allowed for Dynavax product.		X
12	Production and In Process Controls, Packaging and Labeling		
12.01	Procure from WEST approved vendors, test, and release raw materials, packaging and if applicable labeling used in manufactured Product.		X
12.02	Establish and document specifications for raw materials, packaging materials and other materials as and to the extent set forth in the WEST Specifications.		X
12.03	Manufacture Product following processes designed to prevent contamination by other material and in accordance with the WEST Specifications.		X
12.05	Label Product to include: identifying code, lot number, and quantity of contents, Manufacturing Date, Expiration Date		X
12.06	Maintain procedures for release of Product by the Quality Unit.		X
13	Storage and Distribution		
13.01	Maintain storage facilities for Product and ensure that during storage and before shipping of the Product appropriate GMP controls are in place to prevent interference.		X
13.02	Have systems for controlling quarantined, rejected or recalled Product. Segregate rejected or recalled Product.		X
13.03	Qualify packaging for shipment of Product. Only released Product is made available for the shipment to location designated by Dynavax. Product samples required for testing may be shipped prior to release of the product.		X
14	Laboratory Controls in place at WEST laboratories where sterile Product release testing is performed		
14.01	Have written procedures for sample management, testing, approval, disposition and the recording, storage, and archiving of laboratory data.		X

21.

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14.02	Have appropriate specifications, including microbiological testing as applicable, and test procedures for the applicable sterile Product.		X
14.03	Test Released Product in accordance with approved methods and WEST Specifications using calibrated equipment.		X
14.04	Have a program for qualification, calibration, and preventative maintenance of all analytical equipment.		X

22.

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In Witness Whereof, the parties hereto have caused their duly authorized officers to execute this Agreement.

WEST PHARMACEUTICAL SERVICES, INC.

DYNAVAX

By: /s/ Françoise Botte

By: /s/ Tas Heinrich

Name: Françoise Botte

Name: Tas Heinrich

Title: Director Quality PPS

Title: Vice President – Global Quality

Date: January 8, 2015

Date: January 15, 2015



Attachments:

- Attachment - 1: List of the Contacts from both parties - West and Dynavax
- Attachment - 2: Copy of current product specification
- Attachment - 3: West's customer change notification policy
- Attachment - 4: Drawing Article 2345



Attachment — 1: List of the Contacts West and Dynavax

	West	Dynavax
	Quality Assurance	Quality Assurance
Name	XXXX	XXXX
Title	Site QA Manager	Sr. QA Manager
Phone	XXXX	XXXX
Email		
Name		XXXX
Title		XXXX
Phone		XXXX
Email		XXXX

	Account Manger	Technical Operation
Name	XXXX	XXXX
Title		
Phone		
Email		



Attachment — 2: Copy of West Product Specification

[*] { Redacted content comprises approximately 5 pages. }

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Attachment — 3: West's customer change notification policy

April 08, 2014

West Pharmaceutical Services, Inc. Policy on Change Notification

Objectives

The objectives of the West change process is to assure that every change to West's products is evaluated to determine its potential impact to material of composition, design, form, fit or function and therefore its potential impact on the safety, quality, identity or purity of the products supplied to its customers.

Policy

West recognizes that customers should be notified of important changes, in the products we supply in order to avoid potential risk to the customers' products and, in turn, the patients they serve. Therefore, West has established internal risk-based change-control procedures to manage and track all changes within the West manufacturing network and to notify the customer so that the customer can evaluate their impact in a timely fashion. Changes are evaluated based on three established categories:

- **Major Change** – A change that alters the product's physical and/or chemical properties outside of established specifications or is likely to impact the performance or quality of the west product. Examples of a Major Change are a change in manufacturing facility location or raw material.
- **Moderate Change** – A change that may alter the product's physical and/or chemical properties outside of established specifications or may impact the performance or quality of ;the West product. Examples of a Moderate Change are a change in test method that is not compendial in nature or a change in manufacturing method or process.
- **Minor Change** – A change that is unlikely to alter the product's physical and/or chemical properties outside of established specifications or unlikely to impact the performance or quality of the West product. Examples of a Minor change are a change to a more stringent product specification or a change in quality control laboratory location using the same methods.

Timing of Notification

West will provide written notice to customers as follows:

- **Major Changes** – one year, whenever possible, but no less than 90 days, prior to the change.
- **Moderate Changes** – at least 90 days prior to the change.
- **Minor Changes**•– at the discretion of West.



Reinhold Zimmermann
West Global Vice President of Quality

Attachment — 4: Drawing 2345

[*]

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

	For the Year Ended December 31,				
	2017	2016	2015	2014	2013
	(In thousands)				
Earnings					
Loss from continuing operations before income taxes	\$ (95,154)	\$ (112,444)	\$ (106,794)	\$ (90,722)	\$ (66,720)
Fixed charges	753	630	1,108	508	509
Earnings, as defined	<u>\$ (94,401)</u>	<u>\$ (111,814)</u>	<u>\$ (105,686)</u>	<u>\$ (90,214)</u>	<u>\$ (66,211)</u>
Fixed charges:					
Interest expense	\$ -	\$ -	\$ 572	\$ 35	\$ -
Estimated interest component of rent expenses	753	630	536	473	509
Total fixed charges	<u>\$ 753</u>	<u>\$ 630</u>	<u>\$ 1,108</u>	<u>\$ 508</u>	<u>\$ 509</u>
Preferred stock deemed dividend					
	-	-	-	-	8,469
Total fixed charges and preferred dividend	<u>\$ 753</u>	<u>\$ 630</u>	<u>\$ 1,108</u>	<u>\$ 508</u>	<u>\$ 8,978</u>
Deficiency of earnings available to cover fixed charges and preferred stock dividends⁽¹⁾	<u>\$ (95,154)</u>	<u>\$ (112,444)</u>	<u>(106,794)</u>	<u>\$ (90,722)</u>	<u>(75,189)</u>

(1): Adjusted earnings, as described above, were insufficient to cover fixed charges in each year.

List of Subsidiaries

Dynavax GmbH

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3ASR Nos. 333-219781 and 333-207966) of Dynavax Technologies Corporation and in the related Prospectuses, and
- (2) Registration Statements (Form S-8 Nos. 333-113220, 333-136345, 333-145094, 333-152819, 333-157741, 333-164255, 333-171552, 333-190313, 333-197838, 333-204506, 333-211747, 333-218470 and 333-221832) pertaining to the 1997 Equity Incentive Plan, the 2004 Stock Incentive Plan, the 2004 Employee Stock Purchase Plan, the 2010 Employment Inducement Award Plan, the 2011 Equity Incentive Plan, 2014 Employee Stock Purchase Plan, and the Inducement Award Plan of Dynavax Technologies Corporation;

of our reports dated March 8, 2018, 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, 2017.

/s/ Ernst & Young LLP

San Francisco, California
March 8, 2018

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 8, 2018

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Eddie Gray, Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Annual Report on Form 10-K for the period ended December 31, 2017 (the "Annual Report"), to which this Certificate is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 8th day of March, 2018.

By: _____ /s/ EDDIE GRAY

**Eddie Gray
Chief Executive Officer
(Principal Executive 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 Securities Exchange Act of 1934, as amended (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**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Michael Ostrach, Chief Financial Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Annual Report on Form 10-K for the period ended December 31, 2017 (the "Annual Report"), to which this Certificate is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 8th day of March, 2018.

By: _____ /s/ MICHAEL OSTRACH

**Michael Ostrach
Chief Financial Officer
(Principal Financial 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 Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.