DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 13, 2017

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, 2016

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

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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

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

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, $0.001 Par Value	The NASDAQ Stock Market LLC
Preferred Shares Purchase Rights	

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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2016 as reported on the NASDAQ Capital Market, was approximately $409,000,000. 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 9, 2017, the registrant had outstanding 44,352,830 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2017 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, 2016.

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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 develop and timely achieve regulatory approval for HEPLISAV-B™, our ability to successfully develop and obtain regulatory approval of our early stage product candidates, SD-101 and DV281, and our other early stage compounds, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, our ability to commercialize our product candidates, including HEPLISAV-B, 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 o variations or comparable terminology.

Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in “Item 1A—Risk Factors” and “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this document. No assurance can be given that the risk factors described in this Annual Report on Form 10-K are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.

This Annual Report on Form 10-K includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners. 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 clinical-stage immunotherapy company focused on leveraging the power of the body’s innate and adaptive immune responses through toll-like receptor (“TLR”) stimulation. Our current product candidates are being investigated for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma.

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.

Development Programs

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

Product Candidate	Combination	Indication(s)	Stage of Development	Partner
HEPLISAV-B		Adult Hepatitis B prevention	Phase 3	
AZD1419		Asthma Disease Modification	Phase 2	AstraZeneca[1]
Immuno-oncology				
SD-101	Pembrolizumab (anti-PD1)	Melanoma	Phase 2	Merck & Co[2]
SD-101	Pembrolizumab (anti-PD1)	Head and Neck Squamous Cell Carcinoma	Phase 2	Merck & Co[2]
SD-101	Anti-IL10	Multiple Malignancies	Phase 1	Merck & Co[3]
DV281	Anti-PD1	Non-small Cell Lung Cancer	Phase 1 planned for Q2 2017	
DV230F		Liver Tumors	Preclinical	
DV1001		TLR 7&8 agonist for multiple malignancies	Preclinical	

[1] AstraZeneca is funding and conducting the study and has licensed worldwide commercial rights.

[2] Under clinical collaboration with Merck & Co. Dynavax is funding the study and maintains all commercial rights to SD-101.

[3] Study funded and conducted by Merck & Co. Dynavax retains all commercial rights to SD-101.

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 candidate, SD-101, 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 TLR 9 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 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 & Co. We have expanded this trial to include head and neck squamous cell carcinoma, another approved indication for KEYTRUDA. In addition, under this clinical collaboration, Merck is conducting a Phase 1 trial in multiple malignancies with SD-101 in combination with their investigational anti-IL10 compound.

Additionally there are ongoing and planned investigator sponsored studies to support our strategy to develop SD-101 in combination with multiple checkpoint inhibitors and other agents in multiple indications.

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. We are conducting a 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.

In October 2014, we initiated a Phase 1/2 multicenter clinical trial of intratumoral administration of SD-101 in adults with untreated low-grade B-cell lymphoma. Key objectives of this study were to assess the systemic, or abscopal, effect on non-injected lesions and to measure levels of CD8+ T cells in the injected site. In December of 2016 we reported interim clinical data from 28 evaluable patients demonstrating tumor regression in untreated tumor sites in a majority of the patients and increases in CD8+ cells were observed in the injected tumor, which correlated with abscopal tumor shrinkage.

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 March 2017, we reported results from the Phase 1 dose escalation part of the study, evaluating 17 patients for efficacy and 22 patients for safety. In patients naïve to anti-PD-1 treatment, responses were observed in six out of seven patients, for an overall response rate of 86%. This includes two (29%) complete responses and four (57%) partial responses. Target tumor shrinkage was observed in all 7 evaluable patients. In 10 patients with progressive disease who initiated KEYTRUDA anti-PD-1 monotherapy prior to enrollment, one partial response was observed and five patients had stable disease while receiving KEYTRUDA and SD-101, with four of the 10 patients experiencing target tumor shrinkage. In early 2017 we completed the initial dose escalation phase and have begun the expansion phase of the trial. In this expansion phase patients will be stratified into two groups, anti-PD1 therapy naïve patients and patients with progressive disease while on anti-PD1 therapy.

SD-101 in combination with KEYTRUDA generally was well-tolerated. No dose-limiting toxicities of the combination were observed in any dose cohort, and a maximum tolerated dose was not identified. The most common treatment-emergent adverse events were injection site reactions and transient grade 1 to 2 flu-like symptoms, including fever, chills and myalgia that respond to over the counter medications such as acetaminophen. The study

also includes biomarker assessments, suggesting that treatment with SD-101 and KEYTRUDA resulted in elevation of gene signatures consistent with an increase in Th1 immune cell types as well as an increase in immune cell infiltrates such as CD8+ T-cells in the tumor microenvironment.

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 have expanded the combination study with KEYTRUDA to include a Phase 2 trial in patients with recurrent or metastatic head and neck squamous cell cancers.

SD-101 in combination with MK-1966 (monoclonal antibody against IL-10)

Under our clinical collaboration, Merck has initiated a Phase 1 dose ranging study combining their monoclonal antibody against IL10 with SD-101.

DV281 – Inhaled TLR 9 agonist for lung cancer

We pioneered the development of an inhaled TLR9 agonist for asthma. The lead product candidate, AZD1419, was developed under a collaboration with AstraZeneca and 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, is planned to enter clinical trials for NSCLC, in combination with anti-PD-1 therapy, in the second quarter of 2017.

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.

HEPLISAV-B

Our most advanced product candidate is HEPLISAV-B, an investigational adult hepatitis B vaccine. HEPLISAV-B combines 1018, a 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 earlier protection with fewer doses than a currently approved hepatitis B vaccine and a similar adverse event profile. Our original Biologics License Application (BLA) was submitted to the U.S. Food and Drug Administration (FDA) in April 2012. FDA issued a Complete Response Letter (CRL) to Dynavax in February 2013 requesting an additional clinical trial to increase the safety database.

In March 2016, we resubmitted the BLA for HEPLISAV-B to the FDA to add more than 5,000 subjects to the HEPLSIAV-B safety database. The total safety database for HEPLISAV-B currently includes 10,038 participants. The FDA issued a CRL to Dynavax in November 2016 requesting information regarding several topics, including clarification of specific adverse events of special interest (AESIs), a numerical imbalance in a small number of cardiac events in a single study, new analyses of the integrated safety data base across different time periods, and post-marketing commitments. We resubmitted the BLA in February 2017 and the FDA has established August 10, 2017 as the Prescription Drug User Fee Act action date.

In order to maintain the ability to pursue HEPLISAV-B through the review period we enacted a restructuring plan to suspend manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B. If the product is approved, we plan to use existing stockpiled inventory to support initial sales.

HEPLISAV-B Potential Commercial Opportunity

Dynavax has worldwide commercial rights to HEPLISAV-B. Our only pending request for regulatory approval is in the U.S., so our initial commercialization efforts will be in the U.S.. 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"). Key market segments for these products consist of persons considered to be at high risk for hepatitis B virus ("HBV") infection and include people with multiple sexual partners or injection drug use, healthcare workers and first responders, international travelers, chronic liver disease patients and, in the U.S., people with diabetes mellitus (type 1 and type 2).

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

Autoimmune and Inflammatory Diseases

We also have clinical and preclinical programs focused on therapeutics for autoimmune and inflammatory diseases.

AZD1419 for Asthma

AZD1419 is being developed for the treatment of asthma pursuant to a collaboration with AstraZeneca AB ("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. On the basis of those results, the parties agreed to bypass a planned Phase 1b trial and proceed directly to Phase 2. AstraZeneca initiated a Phase 2 trial in asthma patient during 2016, which AstraZeneca will fully fund and conduct.

Under our September 2006 Research Collaboration and License Agreement with AstraZeneca, as amended, remaining potential milestone payments to us total approximately $100 million based on the achievement of certain development and regulatory objectives. In addition, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

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, 2016, our intellectual property portfolio included over 30 issued U.S. patents, over 260 issued or granted foreign patents and over 40 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 investigational vaccine that will expire in 2018, and have corresponding issued patents in several major European and other countries. 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 2017 to 2036.

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

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

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies, including Pfizer, Inc. ("Pfizer"), as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions owned or licensed to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use or sell any products. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering HBsAg, a component of HEPLISAV-B. In addition, the Institut Pasteur owns or has exclusive licenses to patents covering HBsAg. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. In order to commercialize HEPLISAV-B, we may be involved in litigation or licensing in respect of some or all of these patents. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK, their licensors or the Institut Pasteur may bring claims against us.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. The existence of third-party patent applications and patents could significantly reduce the coverage of the patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. For example, Pfizer has issued U.S. and foreign patent claims as well as patent claims pending with the PTO and foreign patent offices that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of TLR agonist other than with respect to HEPLISAV-B, for which we have a license. Litigation or any other proceedings, such as patent interferences, could result in substantial costs to and diversion of effort by us, and an adverse outcome in a court or patent office could subject us to significant liabilities, require disputed rights to be licensed from other parties, or require us to cease using some of our technology. We may not prevail 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.

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..

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

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

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

- completion of preclinical laboratory tests, preclinical studies and formulation studies;
- submission to the regulatory authority of a clinical application for a new drug or biologic which must become effective before clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug or biologic for each proposed indication;
- demonstration of the consistent manufacturing of drug substance and drug product;
- the submission of a new drug application to the regulatory authority; and
- regulatory review and approval of the application before any commercial marketing, sale or shipment of the drug or biologic.

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

To secure regulatory authority approval, we must submit extensive non-clinical and clinical data, adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use, and other supporting information to the regulatory authority. The number of preclinical studies and clinical trials that will be required for FDA and foreign regulatory agency approvals varies depending on the product candidate, the disease or condition for which the product candidate is in development and regulations applicable to any particular drug candidate. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval or clearance. Further, the results from preclinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. In addition, the development of the drug substance and drug product may require manufacturing modifications to ensure future regulatory acceptance. The approval process takes many years, requires the expenditures of substantial resources, and involves post-marketing surveillance.

Delays experienced during the approval process may materially reduce the period during which we will have exclusive rights to exploit patented products or technologies. Delays can occur at any stage of drug development and as a result of many factors, certain of which are not under our control, including but not limited to the following:

- lack of efficacy, or incomplete or inconclusive results from clinical trials;
- unforeseen safety issues;
- failure by investigators to adhere to protocol requirements, including patient enrollment criteria;
- slower than expected rate of patient recruitment;
- failure by subjects to comply with trial protocol requirements;
- inability to follow patients adequately after treatment;
- inability to qualify and enter into arrangements with third parties to manufacture sufficient quality and quantities of materials for use in clinical trials;
- failure by a contract research organization to fulfill contractual obligations; and
- adverse changes in regulatory policy during the period of product development or the period of review of any application for regulatory approval or clearance.

The FDA or foreign regulatory agency may also require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Following approval, we may be required to conduct additional post-marketing studies. The regulatory authority may withdraw product approvals if we do not continue to comply with regulatory standards or if problems occur following initial marketing.

Non-clinical studies involve laboratory evaluation of product characteristics or animal studies to assess the initial efficacy and safety of the product. The FDA or other foreign regulatory agency, under its good laboratory practices regulations, regulates certain non-clinical studies. Research and preclinical studies do not involve the introduction of a product candidate in human subjects. These activities involve identification of potential product candidates, modification of promising candidates to optimize their biological activity, as well as preclinical studies to assess safety and effectiveness in animals. In clinical trials, the product candidate is administered to humans. Violations of these regulations can, in some cases, lead to invalidation of those studies, requiring these studies to be repeated. The results of these tests, together with manufacturing information and analytical data, are submitted to the regulatory authority as part of a clinical application, which must be approved by the regulatory authority before we can commence clinical investigations in humans.

Clinical trials involve the administration of the investigational product to humans under the supervision of a qualified principal investigator. We must conduct our clinical trials in accordance with current Good Clinical Practices (“GCP”) regulations under protocols submitted to applicable regulatory authorities as part of the clinical application. GCP regulations mandate comprehensive documentation for the clinical protocol, record keeping, training, and facilities including computers. Quality assurance and inspections are designed to ensure that these GCP standards are achieved. Additionally, each clinical trial must be approved and conducted under the auspices of an Institutional Review Board (“IRB”) or Independent Ethics Committee and with patient informed consent. The IRB will consider, among other

matters, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial.

The stages of the regulatory process include clinical trials in three sequential phases that may overlap. Phase 1 clinical trials typically involve the administration of a product candidate into a small group of healthy human subjects. These trials are the first attempt to evaluate a drug's safety, determine a safe dose range and identify side effects. During Phase 2 trials, the product candidate is introduced into patients who suffer from the medical condition that the product candidate is intended to treat. Phase 2 studies are designed to evaluate whether a product candidate shows evidence of effectiveness, to further evaluate dosage, and to identify possible adverse effects and safety risks. When Phase 2 evaluations demonstrate that a product candidate appears to be both safe and effective, Phase 3 trials are undertaken to confirm a product candidate's effectiveness and to test for safety in an expanded patient population. If the results of Phase 3 trials appear to confirm effectiveness and safety, the data gathered in all phases of clinical trials form the basis for an application for regulatory approval of the product candidate.

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

If our products are approved for sale, we will be subject to further regulatory requirements under federal and state provisions such as federal "sunshine" laws, anti-kickback laws, false claims laws and state law equivalents of those and other regulations. We are also subject to various federal, state, local and foreign laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

MANUFACTURING

We rely on our facility in 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, if approved, 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.

RESEARCH AND DEVELOPMENT

Conducting a significant amount of research and development has been central to our business model. Our research and development expenses were $84.5 million, $86.9 million and $84.6 million for the years ended December 31, 2016, 2015 and 2014, 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, 2016, we had 251 full-time employees, including 142 employees in our headquarters in Berkeley, California and 109 employees in our office and manufacturing facility in Düsseldorf, Germany. As of February 28, 2017, we had 196 employees, including 97 full-time employees in Berkeley, California and 99 employees in Düsseldorf, Germany, many of whom are part-time due to a furlough program initiated in January 2017.

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

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

Risks Related to our Business

We are dependent on the success of our product candidates, especially HEPLISAV-B and SD-101, which depend on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals or the delay and additional costs that would be required to obtain regulatory approvals could require us to discontinue operations.

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

For our most advanced product, HEPLISAV-B, we received a second complete response letter ("CRL") in November 2016 ("2016 CRL") from the FDA based upon their review of our BLA filing. In the U.S., our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations ("CROs"); the results of an advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval,

additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our first CRL, received in 2013, HEPLISAV-B was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. While we conducted a study intended to obtain additional safety data information and submitted the study results and additional information regarding our manufacturing controls and facilities to the FDA, after we resubmitted our BLA we received the 2016 CRL from the FDA seeking additional information on several additional topics, including clarification regarding specific adverse events of special interest, a numerical imbalance in a small number of cardiac events in a single study (HBV-23), new analyses of the integrated safety database across different time periods, and post-marketing commitments. We have responded to the 2016 CRL, but there can be no assurance that we will address the outstanding FDA questions in a manner sufficient for approval in the U.S. We currently expect a review period of at least six months from the date of submission of our response to the 2016 CRL.

In February 2014, we announced our withdrawal of our Marketing Authorization Application (“MAA”) for approval 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.

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

Failure to receive approval or significant additional delay in obtaining an FDA decision on whether to approve our BLA for HEPLISAV-B would have a material adverse effect on our business and results of operations, including possible termination of HEPLISAV-B development and further restructuring of our organization. In January 2017, following our receipt of the 2016 CRL, we restructured our business to emphasize our immuno-oncology programs and implemented a reduction in our global workforce of approximately 38 percent. While this reduced our cash outlay, we continue to maintain expenditures relating to HEPLISAV-B and our immuno-oncology programs remain at an early stage and will require additional funding. Even if HEPLISAV-B is approved, the labeling approved by the relevant regulatory authority may restrict how and to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

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

The FDA may require more clinical trials for our product 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.

We are currently undertaking clinical trials of SD-101, 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 involves combination studies with other oncology agents. While we believe that this combination agent approach increases the potential for success, our clinical trials involving SD-101 are and will continue to be dependent 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, 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.

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In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by 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.

SD-101, HEPLISAV-B 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 our most advanced such as 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 have no commercialization experience, and the time and resources to reinstitute manufacturing and develop sales, marketing and distribution capabilities for HEPLISAV-B are significant. If we fail to achieve and sustain commercial success for HEPLISAV-B, either independently or with a partner, our business would be harmed.

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

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

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

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including 1018 and SD-101, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, fill and finish. In connection with our restructuring in January 2017, we elected to retain, but furlough, the majority of the workforce in Düsseldorf supporting the manufacture of HEPLISAV-B and utilize the existing stockpiled inventory of HEPLISAV-B to meet initial demand if the product is approved. If HEPLISAV-B is approved, we will need to re-activate our facility in Düsseldorf and scale up to meet demand in excess of current supply. Regulatory or other limitations on our ability to re-activate our manufacturing facility, or the termination or interruption of relationships with key suppliers may result in higher cost or delays in our product development or commercialization efforts

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.

We utilize our facility in Düsseldorf to manufacture rHBsAg for HEPLISAV-B. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with GMP regulations. There can be no assurance that the FDA will find our manufacturing controls and facilities to be acceptable to support the approval of HEPLISAV-B.

In addition, we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit, delay or disrupt the commercialization of HEPLISAV-B or our other product candidates and could result in significant expense.

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

We and our third party 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 burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;

- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
    - legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

We have withdrawn our MAA for HEPLISAV-B in Europe and we may not be able to provide sufficient data or respond to other comments to our previously filed MAA sufficient to obtain regulatory approvals in Europe in a reasonable time period or at all. Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, 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 and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

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

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV-B where existing products are already marketed. While 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, there can be no assurance that HEPLISAV-B would launch with stable pricing and favorable reimbursement.

Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is uncertain. We will

have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV-B, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

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

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

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

We may need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV-B, if approved. Failure to obtain a collaborative relationship for HEPLISAV-B, particularly in markets requiring extensive sales efforts, may significantly impair the potential for this product. 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 therapies to prevent or treat cancer and infectious and inflammatory diseases. For example, if it is approved in the future, HEPLISAV-B will compete in the U.S. with established hepatitis B vaccines marketed by Merck and GSK and outside the U.S. with vaccines from those companies and several additional established pharmaceutical companies. The field of oncology therapeutics is extremely competitive, with numerous biotechnology and pharmaceutical companies developing therapies for all of the targets the Company is pursuing. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates.

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

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

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

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud 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. If we obtain approval for and commercialize a vaccine or other product, our interactions with physicians and others in a position to prescribe or purchase our products will be subject to a legal regime designed to prevent healthcare fraud and abuse. 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 Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- laws that require transparency regarding financial arrangements with health care professionals, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act ("PPACA") and state laws;
- the federal Health Insurance Portability and Accountability Act of 1997 ("HIPAA"), which created 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 and Criminal 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 healthcare fraud and abuse laws provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

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

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to criminal and/or civil sanctions, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may 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. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

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

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

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

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

in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

We are involved in legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations.

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.

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 Finances and Capital Requirements

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $812.2 million as of December 31, 2016. To date, our revenue has resulted from collaboration agreements, government and

private agency grants and services and license fees from our customers, including the customers of our wholly-owned subsidiary Dynavax GmbH. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and our efforts to further develop and seek regulatory approval of HEPLISAV-B.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV-B or any of our other product candidates can be successfully developed, financed or commercialized in a timely manner based on our current plans. We will not be able to achieve approval or generate meaningful sales without significant additional resources. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales and entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms.

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

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

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

The cash requirements of our current operations will be significantly impacted by the FDA decision regarding our response to its 2016 CRL for HEPLISAV-B. Although we believe we have current funds for the next twelve months based on our current operational plans, cash, cash equivalents and marketable securities on hand, we expect that if HEPLISAV-B is approved by the FDA, we will require additional capital following approval, in particular if we fail to enter into a third party collaboration following approval.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Our ability to raise additional capital in the equity and debt markets 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, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. Equity or other financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Risks Related to our Intellectual Property

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

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party’s patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly,

time consuming and delay or prevent development or commercialization of our product candidates.

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

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of 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. To the extent we are able to commercialize HEPLISAV-B in the U.S. while these patents remain in force, Merck, GSK or their respective licensors or the Institut Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in 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 or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

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

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

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

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be

able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights, we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

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

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

- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and BLA filing and communications, from the FDA or other regulatory agencies, including a decision by the FDA regarding our response to its 2016 CRL for HEPLISAV-B and the potential for an advisory committee meeting for HEPLISAV-B;
- 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 2013 that the FDA would not approve HEPLISAV-B for sale without a significant additional clinical study, and 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, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the SEC 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, 2016 we had 38,598,618 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.

Future sales of our common stock, including pursuant to our 2015 ATM Agreement with Cowen, would cause immediate dilution and could adversely affect the market price of our common stock. Under our universal shelf registration statement filed by us in November 2015, as amended in February 2017, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings in the aggregate amount of up to $200,000,000, which includes amounts sold pursuant to our 2015 ATM. 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, 2016, we lease approximately 55,200 square feet of laboratory and office space in Berkeley, California under agreements expiring in June 2018. We also lease approximately 5,600 square meters of laboratory

and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.

ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of business, 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 will be 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.

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 Soontjens v. Dynavax Technologies Corporation et. al., ("Soontjens") and Shumake v. Dynavax Technologies Corporation et al., ("Shumake"). The Soontjens 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's deadline to file a consolidated amended complaint is March 17, 2017.

Additionally, on January 18, 2017, the Company was made aware of a derivative complaint that a purported stockholder of the Company intends to file in the Superior Court of California for the County of Alameda against certain of the Company's current executive officers and directors. Following this, 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 yet-to-be filed complaint that the Company was made aware of on January 18, 2017. 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. Plaintiffs are seeking unspecified monetary damages, including restitution from defendants, corporate governance changes, attorneys' fees and costs, and other relief.

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.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the NASDAQ 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
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
2015		
First Quarter	$26.89	$15.80
Second Quarter	$24.60	$18.53
Third Quarter	$32.49	$22.61
Fourth Quarter	$28.49	$21.65

As of March 7, 2017, there were approximately 55 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 13,800 as the number of record holders excludes shares held in "street name" through brokers.

Dividends

We have never paid any cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

		(c) Total Number of Shares	(d) Maximum Number (or Approximate Dollar Value)

Period	(a) Total Number of Shares (or Units) Purchased[1] (In thousands)	(b) Average Price Paid per Share (or Unit)	(or Units) Purchased as Part of Publicly Announced Plans or Programs	of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2016 to October 31, 2016	-	$ -	-	-
November 1, 2016 to November 30, 2016	-	-	-	-
December 1, 2016 to December 31, 2016	42,511	4.62	-	-
Total	42,511	$ 4.62	-	-

(1) During December 2016, the Company withheld 42,511 shares of common stock on behalf of its employees for employee tax obligations due upon vesting of restricted stock.

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, 2016, 2015 and 2014 and the Consolidated Balance Sheets Data as of December 31, 2016 and 2015 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, 2013 and 2012 and the Consolidated Balance Sheets Data as of December 31, 2014, 2013 and 2012 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,				
	2016	2015	2014	2013	2012
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Total revenues	$11,043	$4,050	$11,032	$11,251	$9,714
Operating expenses:					
Research and development	84,493	86,943	84,580	50,870	49,146
General and administrative	37,257	22,180	17,377	25,943	28,164
Unoccupied facility expense	-	-	386	926	-
Total operating expenses	121,750	109,123	102,343	77,739	77,310
Loss from operations	(110,707)	(105,073)	(91,311)	(66,488)	(67,596)
Other (expense) income:					
Interest income	755	205	191	116	291
Interest expense	-	(572)	(35)	-	(2,351)
Other (expense) income, net	(2,492)	317	433	(348)	(293)
Loss on extinguishment of debt[1]	-	(1,671)	-	-	-
Net loss	(112,444)	(106,794)	(90,722)	(66,720)	(69,949)
Net loss attributable to Dynavax	(112,444)	(106,794)	(90,722)	(66,720)	(69,949)
Preferred stock deemed dividend[2]	-	-	-	(8,469)	-
Net loss allocable to Dynavax common stockholders	$(112,444)	$(106,794)	$(90,722)	$(75,189)	$(69,949)
Basic and diluted net loss per share allocable to Dynavax common stockholders	$(2.92)	$(3.25)	$(3.45)	$(3.83)	$(4.10)
Shares used to compute basic and diluted net loss per share allocable to Dynavax common stockholders	38,506	32,881	26,289	19,628	17,047

(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,				
	2016	2015	2014	2013	2012

	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$81,415	$196,125	$122,652	$189,376	$125,130
Working capital	69,563	171,161	107,158	176,186	109,173
Total assets	109,680	216,633	138,290	204,622	139,752
Long-term debt[1]	-	-	9,559	-	-
Accumulated deficit	(812,171)	(699,727)	(592,933)	(502,211)	(435,491)
Total stockholders' equity	89,201	187,079	100,482	186,294	114,826

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

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

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

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

Overview

We are a clinical-stage immunotherapy company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our current product candidates are being investigated for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma.

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. We are conducting a 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.

HEPLISAV-B™ is our investigational adult hepatitis B vaccine. In March 2016, we resubmitted our application to market HEPLISAV-B to the FDA and in November 2016 the FDA issued a Complete Response Letter requesting information regarding several topics, including clarification of specific adverse events of special interest (AESIs), a numerical imbalance in a small number of cardiac events in a single study, new analyses of the integrated safety data base across different time periods, and post-marketing commitments. We resubmitted the application in February 2017 and the FDA has established August 10, 2017 as the Prescription Drug User Fee Act action date.

In order to maintain the ability to pursue HEPLISAV-B through the review period, in January 2017 we enacted a restructuring plan to suspend manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B. In addition, we reduced our global workforce by 38 percent and expect to incur restructuring costs related to one-time employee termination benefits, currently estimated to be $3.0 million, which will be primarily paid in cash in the first quarter of 2017. If HEPLISAV-B is approved, we plan to use existing stockpiled inventory to support initial commercial demand.

AZD1419 is being developed by AstraZeneca AB ("AstraZeneca") for the treatment of asthma pursuant to a collaboration and license agreement. AstraZeneca initiated a Phase 2a trial in 2016.

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of $812.2 million as of December 31, 2016. These losses have resulted principally from costs incurred in connection with research and development activities, compensation and other related personnel costs and general corporate expenses. Research and development activities include costs of outside contracted services including clinical trial costs, manufacturing and

process development costs, research costs and other consulting services. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. General corporate expenses include outside services such as accounting, consulting, business development, commercial, investor relations, insurance services and legal costs. Our operating results may fluctuate substantially from period to period principally as a result of the timing of preclinical activities and other activities related to clinical trials for our drug candidates.

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. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly SD-101, our lead investigational cancer immunotherapeutic product candidate, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue our development activities and if HEPLISAV-B is approved, we will need additional funding or a partnership to enable commercialization. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development programs while we seek strategic alternatives.

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 critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

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

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 over our estimated performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize revenues for costs that are reimbursed under collaborative agreements as the related research and development costs are incurred.

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

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether milestones meet the criteria to be considered substantive. The conditions include: (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. As a result of our analysis, we may consider our development milestones to be substantive. Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement. All revenue recognized to date under our collaborative agreements has been nonrefundable.

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.

Recent Accounting Pronouncements

Accounting Standards Update ("ASU") 2014-09

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance codified in ASC 606, Revenue Recognition — Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition, which 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 are currently evaluating the impact (if any) this guidance will have on our consolidated financial statements. We anticipate adoption of ASC 606 using the modified retrospective method with a cumulative catch-up adjustment to the opening balance sheet of retained earnings at the effective date, during the first quarter of 2018. The Company will continue to review variable consideration, potential disclosures, and the method of adoption in order to complete the evaluation of the impact on the consolidated financial statements. In addition, the Company will continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact the current conclusions.

Results of Operations

Revenues

Revenues consist 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):

	Year Ended December 31,			Increase (Decrease) from 2015 to 2016		Increase (Decrease) from 2014 to 2015	
Revenues:	2016	2015	2014	$	%	$	%
Collaboration revenue	$9,778	$2,765	$7,933	$ 7,013	254 %	$ (5,168)	(65)%
Grant revenue	381	683	2,688	(302)	(44)%	(2,005)	(75)%
Service and license revenue	884	602	411	282	47 %	191	46 %
Total revenues	$11,043	$4,050	$11,032	$ 6,993	173 %	$ (6,982)	(63)%

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.

2015 versus 2014

Collaboration revenue decreased due to winding down of work performed for the Phase 1 clinical trial for AZD1419, extension of the estimated performance period for the $5.4 million payment received from AstraZeneca in March 2014, and expiration of our collaboration agreement with GSK in 2014. Grant revenue decreased due to expiration of our National Institute of Health's National Institute of Allergy and Infectious Diseases ("NIAID") contracts for adjuvant development in 2014. The overall decrease was partially offset by an increase of service and license revenue due to revenue received from manufacturing services performed on behalf of a third party.

We expect our collaboration revenue from existing collaboration agreements to decrease in 2017 as compared to 2016, as milestones under our existing agreements, related mainly to development and regulatory objectives, are anticipated to occur subsequent to 2017.

Research and Development

Research and development expense consists primarily of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the years ended December 31, 2016, 2015 and 2014, approximately

67%, 80% and 80%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our investigational adult hepatitis B vaccine, HEPLISAV-B. The following is a summary of our research and development expense (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2015 to 2016		Increase (Decrease) from 2014 to 2015	
Research and Development:	2016	2015	2014	$	%	$	%
Compensation and related personnel costs	$34,333	$30,183	$24,352	$4,150	14 %	$5,831	24 %
Outside services	32,540	45,495	50,923	(12,955)	(28)%	(5,428)	(11)%
Facility costs	10,878	7,142	6,437	3,736	52 %	705	11 %
Non-cash stock-based compensation	6,742	4,123	2,868	2,619	64 %	1,255	44 %
Total research and development	$84,493	$86,943	$84,580	$(2,450)	(3)%	$2,363	3 %

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.

2015 versus 2014

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 share-based awards granted to employees. Outside services expense decreased primarily due to lower activity related to HBV-23, which concluded in late 2015. Facility costs increased due to an overall increase in employee headcount.

General and Administrative

General and administrative expense consists primarily of compensation and related personnel costs; costs for outside services such as accounting, commercial development, consulting, business development and investor relations and for 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 general and administrative expenses (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2015 to 2016		Increase (Decrease) from 2014 to 2015	
General and Administrative:	2016	2015	2014	$	%	$	%
Compensation and related personnel costs	$11,814	$8,765	$6,637	$3,049	35 %	$2,128	32 %
Outside services	14,400	5,588	4,325	8,812	158 %	1,263	29 %
Legal costs	2,458	1,721	2,491	737	43 %	(770)	(31)%
Facility costs	1,201	912	703	289	32 %	209	30 %
Non-cash stock-based compensation	7,384	5,194	3,221	2,190	42 %	1,973	61 %
Total general and administrative	$37,257	$22,180	$17,377	$15,077	68 %	$4,803	28 %

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.

2015 versus 2014

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 the hiring of consultants for administrative and commercial development services. Non-cash stock-based compensation increased due to increased annual stock option grants in 2015 and a full year of expense related to 2014 annual option grants recognized in 2015. Legal costs decreased as certain ongoing litigation expenses incurred during 2015 were covered under our insurance. Facility costs increased due to an increase in rent expense as the portion of our facility in Berkeley, California, previously accounted for as a sublease, was occupied by us during 2015.

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 (expense) income, net includes gains and losses on foreign currency transactions. In addition, other (expense) income, 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 2015 to 2016		Increase (Decrease) from 2014 to 2015	
	2016	2015	2014	$	%	$	%
Interest income	$755	$205	$191	$550	268 %	$14	7 %
Interest expense	$-	$(572)	$(35)	$(572)	(100)%	$537	1534 %
Other (expense) income, net	$(2,492)	$317	$433	$(2,809)	(886)%	$(116)	(27)%
Loss on extinguishment of debt	$-	$(1,671)	$-	$(1,671)	(100)%	$1,671	100 %

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 7, Commitments and Contingencies, in our Notes to Consolidated Financial Statements.

2015 versus 2014

Interest income for the year ended December 31, 2015, remained flat compared to the same period in 2014. Interest expense increased due to interest expense related to the Loan Agreement. Other (expense) income, net decreased due to a reduced gain on foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar and withholding taxes paid in Europe as compared to the prior year. During the year ended December 31, 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.

Liquidity and Capital Resources

As of December 31, 2016, we had $81.4 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, 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.

On November 12, 2015, we entered into an At Market Issuance Sales Agreement ("2015 ATM Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell our common stock having aggregate sales proceeds of up to $90 million from time to time through Cowen as our sales agent. We initiated sales under the 2015 ATM Agreement during the first quarter of 2017 and we have received cash of $23.3 million resulting from sales of 5,650,322 shares of common stock, as of March 9, 2017.

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 Issuance Sales Agreement (“2014 ATM Agreement”) with Cowen and Company, LLC., 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.

2015 versus 2014

During the year ended December 31, 2015, we used $92.6 million of cash for our operations primarily due to our net loss of $106.8 million, of which $13.3 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, cash-settled stock based compensation, accretion and amortization on marketable securities and loss on extinguishment of debt. By comparison, during the year ended December 31, 2014, we used $73.7 million of cash for our operations primarily due to a net loss of $90.7 million, of which $8.7 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization and accretion and amortization on marketable securities. Cash used in our operations during 2015 increased by $18.8 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, 2015, cash used in investing activities was $85.8 million compared to $90.6 million of cash provided by investing activities for the year ended December 31, 2014. Cash used in investing activities during the year ended December 31, 2015 included $78.8 million of net purchases of marketable securities compared with $92.3 million of net proceeds from maturities of marketable securities during the same period in 2014. Net cash used in the purchases of equipment increased by $5.3 million compared to the prior year and totaled $7.0 million and $1.7 million in 2015 and 2014, respectively. The increase is due primarily to the purchase of manufacturing equipment for our product candidate, HEPLISAV-B.

During the year ended December 31, 2015 and 2014, cash provided by financing activities was $174.0 million and $9.9 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 ATM Agreement. In 2014 we received proceeds of $9.6 million under a loan agreement and $0.3 million from exercises of options and warrants as well as employee purchases of our common stock under the 2014 Employee Stock Purchase Plan.

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2016, we had cash, cash equivalents and marketable securities of $81.4 million and cash used in operating activities of $107.1 million. We adopted FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40) effective December 31, 2016. We have evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for a period of one year following the date that these financial statements are issued. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly SD-101, our lead investigational cancer immunotherapeutic product candidate, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue our development activities and if HEPLISAV-B is approved, we will need additional funding or a partnership to enable commercialization. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

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

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2016 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2017	2018-2019	2020-2021	2022 and Thereafter
Operating leases	$6,409	$2,560	$ 2,129	$ 1,159	$ 561
Total	$6,409	$2,560	$ 2,129	$ 1,159	$ 561

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

During 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, 2016 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, 2016 and 2015. 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, 2016 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, 2016 and 2015.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical and commercial 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.

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 $0.4 million or $0.5 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, 2016 was $3.6 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2016, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2016 and 2015, 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, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dynavax Technologies Corporation at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2016, 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 13, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 13, 2017

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$24,289	$44,812
Marketable securities available-for-sale	57,126	151,313
Accounts and other receivables	1,342	1,394
Prepaid expenses and other current assets	6,842	2,427
Total current assets	89,599	199,946
Property and equipment, net	17,174	13,804
Goodwill	1,971	2,043
Restricted cash	602	609
Other assets	334	231
Total assets	$109,680	$216,633
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$3,796	$3,433
Accrued research and development	5,048	7,361
Accrued liabilities	11,192	15,337
Deferred revenues	-	2,654
Total current liabilities	20,036	28,785
Other long-term liabilities	443	769
Total liabilities	20,479	29,554
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at December 31, 2016 and December 31, 2015; no shares issued and outstanding at December 31, 2016 and December 31, 2015	-	-
Common stock: $0.001 par value; 69,500 shares authorized at December 31, 2016 and 2015; 38,599 and 38,446 shares issued and outstanding at December 31, 2016 and 2015, respectively	39	38
Additional paid-in capital	904,957	889,698
Accumulated other comprehensive loss	(3,624)	(2,930)
Accumulated deficit	(812,171)	(699,727)
Total stockholders' equity	89,201	187,079
Total liabilities and stockholders' equity	$109,680	$216,633

See accompanying notes.

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Revenues:			
Collaboration revenue	$9,778	$2,765	$7,933
Grant revenue	381	683	2,688
Service and license revenue	884	602	411
Total revenues	11,043	4,050	11,032
Operating expenses:			
Research and development	84,493	86,943	84,580
General and administrative	37,257	22,180	17,377
Unoccupied facility expense	-	-	386
Total operating expenses	121,750	109,123	102,343
Loss from operations	(110,707)	(105,073)	(91,311)
Other (expense) income:			
Interest income	755	205	191
Interest expense	-	(572)	(35)
Other (expense) income, net	(2,492)	317	433
Loss on extinguishment of debt	-	(1,671)	-
Net loss	$(112,444)	$(106,794)	$(90,722)
Basic and diluted net loss per share	$(2.92)	$(3.25)	$(3.45)
Weighted average shares used to compute basic and diluted net loss per share	38,506	32,881	26,289

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Net loss	$(112,444)	$(106,794)	$ (90,722)
Other comprehensive (loss) income:			
Unrealized (loss) gain on marketable securities available-for-sale	(8)	11	32
Cumulative foreign currency translation adjustments	(686)	(1,272)	(1,553)
Total other comprehensive loss	(694)	(1,261)	(1,521)
Total comprehensive loss	$(113,138)	$(108,055)	$ (92,243)

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Preferred Stock					
	Shares	Par Amount	Shares	Par Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2013	26,280	$ 263	43	$ -	$ 688,390	$ (148)	$ (502,211)	$ 186,294
Issuance of common stock upon exercise of stock options and restricted stock awards	5	-	-	-	49	-	-	49
Reverse stock split	-	(237)	-	-	237	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	11	-	-	-	130	-	-	130
Warrants exercised	11	-	-	-	163	-	-	163
Stock compensation expense	-	-	-	-	6,089	-	-	6,089
Total other comprehensive loss	-	-	-	-	-	(1,521)	-	(1,521)
Net loss	-	-	-	-	-	-	(90,722)	(90,722)
Balances at December 31, 2014	26,307	$ 26	43	$ -	$ 695,058	$ (1,669)	$ (592,933)	$ 100,482
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	38,446	$ 38	-	$ -	$ 889,698	$ (2,930)	$ (699,727)	$ 187,079
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	38,599	$ 39	-	$ -	$ 904,957	$ (3,624)	$ (812,171)	$ 89,201

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Operating activities			
Net loss	$(112,444)	$(106,794)	$(90,722)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,257	1,365	1,404
Write-off of assets in progress	862	-	-
Loss (gain) on disposal of property and equipment	91	46	(24)
Accretion of discounts and amortization of premiums on marketable securities	178	660	881
Unoccupied facility expense	-	-	386
Accretion of debt discount related to debt financing	-	(115)	-
Cash-settled portion of stock compensation expense	602	387	-
Stock compensation expense	14,126	9,316	6,089
Loss on extinguishment of debt	-	1,671	-
Changes in operating assets and liabilities:			
Accounts and other receivables	52	(667)	900
Prepaid expenses and other current assets	560	1,631	(2,683)
Restricted cash and other assets	(103)	(211)	277
Accounts payable	1,181	1,246	(523)
Accrued liabilities and other long term liabilities	(11,759)	9,017	4,810
Deferred revenues	(2,654)	(10,111)	5,467
Net cash used in operating activities	(107,051)	(92,559)	(73,738)
Investing activities			
Purchases of marketable securities	(126,754)	(208,936)	(44,807)
Proceeds from maturities of marketable securities	220,760	130,110	137,071
Purchases of property and equipment, net	(7,757)	(6,970)	(1,667)
Net cash provided by (used in) investing activities	86,249	(85,796)	90,597
Financing activities			
Proceeds from issuances of common stock, net	-	183,897	-
Payment of debt	-	(10,988)	-
(Withholding) proceeds from exercise of stock options and restricted stock awards, net	(84)	531	49
Proceeds from Employee Stock Purchase Plan	615	291	130
Proceeds from exercise of warrants	-	228	163
Proceeds from long-term debt, net	-	-	9,559
Net cash provided by financing activities	531	173,959	9,901
Effect of exchange rate changes on cash and cash equivalents	(252)	(303)	(371)
Net (decrease) increase in cash and cash equivalents	(20,523)	(4,699)	26,389
Cash and cash equivalents at beginning of year	44,812	49,511	23,122
Cash and cash equivalents at end of year	$24,289	$44,812	$49,511
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$-	$720	$-

Accrual for litigation settlement and insurance recovery	$4,975	$-	$-
Return of unused development funding to AstraZeneca AB “AstraZeneca” (Note 9)	$7,200	$-	$-
Milestone payment from AstraZeneca (Note 9)	$7,200	$-	$-
Non-cash investing and financing activities:			
Disposal of fully depreciated property and equipment	$2,354	$1,436	$841
Net change in unrealized (loss) gain on marketable securities	$(8)	$11	$32

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 clinical-stage immunotherapy company focused on leveraging the power of the body's innate and adaptive immune response through toll-like receptor ("TLR") stimulation. Our current product candidates are being investigated for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Subsidiaries

In April 2006, we completed the acquisition of Dynavax GmbH, a wholly-owned subsidiary in Düsseldorf, Germany.

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. 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

We have incurred significant operating losses and negative cash flows from operations since our inception. As of December 31, 2016, we had cash, cash equivalents and marketable securities of $81.4 million and cash used in operating activities of $107.1 million. We adopted FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40) effective December 31, 2016. We have evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for a period of one year following the date that these financial statements are issued.

We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly SD-101, our lead investigational cancer immunotherapeutic product candidate, human clinical trials for our other product candidates and additional applications and advancement of our technology. In order to continue our development activities and if HEPLISAV-B™ is approved, we will need additional funding or a partnership to enable commercialization. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold one or more development programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

The Company's ability to raise additional capital in the equity and debt markets is dependent on a number of factors, including, but not limited to, the market demand for the Company's common stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company.

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 throughout the year. Currency translation adjustments arising from period to period are charged or credited to accumulated other comprehensive income (loss) in stockholders' equity. For the years ended December 31, 2016, 2015 and 2014, we reported an unrealized loss of $0.7 million, $1.3 million and $1.6 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, 2016, 2015 and 2014, we reported a gain of $0.2 million, $0.1 million and $0.4 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 income (loss) in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

- Whether the investment has been in a continuous realized loss position for over 12 months;
- the duration to maturity of our investments;
- our intention and ability to hold the 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 2016, 2015 and 2014, 92%, 85% and 96% of our revenues were earned in the United States, respectively, and the remaining revenues were earned in Germany. As of December 31, 2016 and 2015, 17% and 11%, 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. government agency securities, U.S. Treasuries and corporate debt securities. We have not experienced any losses on our cash equivalents and marketable securities.

Our products will require approval from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals have had a material adverse impact on our business and may impact our business in the future.

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 products, product liability, the volatility of our stock price and the need to obtain additional financing.

Long-Lived Assets

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. 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, including intangible assets, whenever events or changes in business circumstances or our planned use of long-lived assets indicate, based on undiscounted future operating cash flows, that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. When an indicator of impairment exists, 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 purchased intangible assets or material 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

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

deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

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 over our estimated performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize revenues for costs that are reimbursed under collaborative agreements as the related research and development costs are incurred.

Contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive

uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether milestones meet the criteria to be considered substantive. The conditions include: (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. As a result of our analysis, we may consider our development milestones to be substantive. Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments based solely upon the performance of our partner. We expect to recognize the contingent payments as revenue upon receipt, provided that all other revenue recognition criteria have been satisfied.

Revenues from manufacturing services are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. 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, 2016.

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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. Additionally, we assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. We have provided a full valuation allowance on our deferred tax assets at December 31, 2016 and 2015 because we believe it is more likely than not that our deferred tax assets will not be realized as of December 31, 2016, and 2015.

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.

Recent Accounting Pronouncements

Accounting Standards Update ("ASU") 2014-09

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance codified in ASC 606, Revenue Recognition, Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition, which 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 are currently evaluating the impact (if any) this guidance will have on our consolidated financial statements. We anticipate adoption of ASC 606 using the modified retrospective method with a cumulative catch-up adjustment to the opening balance sheet of retained earnings at the effective date, during the first quarter of 2018. The Company will continue to review variable consideration, potential disclosures, and the method of adoption in order to complete the evaluation of the impact on the consolidated financial statements. In addition, the Company will continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact the current conclusions.

Accounting Standards Update 2016-02

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires management to recognize lease assets and lease liabilities by lessees for all operating leases. The ASU is effective for annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis, with early application permitted. We are currently evaluating the impact this guidance will have on our consolidated financial statements.

Accounting Standards Update 2016-09

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 modifies several aspects of the accounting for share-based payment transactions, including the accounting for income taxes and classification on the statement of cash flows. The standard becomes effective beginning in the first quarter of 2017. Early adoption is permitted for any entity in any interim or annual period. Therefore, the Company has early adopted this new standard as of December 31, 2016. The adoption of this standard did not have a material impact on our consolidated financial statements as of December 31, 2016.

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.

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):

	Level 1	Level 2	Level 3	Total
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	$18,981	$58,877	$ -	$77,858

	Level 1	Level 2	Level 3	Total
December 31, 2015				
Money market funds	$21,193	$-	$ -	$21,193
U.S. government agency securities	-	17,622	-	17,622
Corporate debt securities	-	152,749	-	152,749
Total	$21,193	$170,371	$ -	$191,564

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.

There were no transfers between Level 1 and Level 2 during the twelve months ended December 31, 2016 and 2015.

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, 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
December 31, 2015				
Cash and cash equivalents:				
Cash	$ 4,561	$ -	$ -	$ 4,561
Money market funds	21,193	-	-	21,193
Corporate debt securities	19,052	7	(1)	19,058
Total cash and cash equivalents	44,806	7	(1)	44,812
Marketable securities available-for-sale:				
U.S. government agency securities	17,628	-	(6)	17,622
Corporate debt securities	133,679	71	(59)	133,691
Total marketable securities available-for-sale	151,307	71	(65)	151,313
Total cash, cash equivalents and marketable securities	$ 196,113	$ 78	$ (66)	$ 196,125

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

	December 31, 2016	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$57,122	$ 57,126
Mature after one year through two years	-	-
	$57,122	$ 57,126

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2016, 2015 and 2014. 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. Property and Equipment

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

	Estimated Useful Life	December 31,	
	(In years)	2016	2015
Manufacturing equipment	5-14	$10,086	$6,880
Lab equipment	5-13	6,280	6,096
Computer equipment	3	4,010	2,577
Furniture and fixtures	3-13	1,566	1,362
Leasehold improvements	5-8[(1)]	8,942	5,768
Assets in progress		2,298	6,645
		33,182	29,328
Less accumulated depreciation and amortization		(16,008)	(15,524)
Total		$17,174	$13,804

(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 $2.3 million, $1.4 million and $1.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

6. Current Accrued Liabilities and Accrued Research and Development

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

	December 31,	
	2016	2015
Payroll and related expenses	$3,753	$5,866
Legal expenses	275	202
Litigation settlements accrual (Note 7)	4,975	-
Third party research expenses	2,784	5,241
Third party development expenses	2,002	2,072
Return of unused development funding to AstraZeneca (Note 9)	-	7,345
Other accrued liabilities	2,451	1,972
Total	$16,240	$22,698

7. Commitments and Contingencies

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space.

Total net rent expense related to our operating leases for the years ended December 31, 2016, 2015 and 2014, was $2.2 million, $2.0 million and $1.7 million, respectively. Deferred rent was $0.3 million and $0.5 million as of December 31, 2016 and 2015, respectively. Accrued loss on lease was $0.3 million and $0.5 million as of December 31, 2016 and 2015, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at December 31, 2016, excluding payments from sublease payments, are as follows (in thousands):

Year ending December 31,	
2017	$2,560
2018	1,491
2019	638
2020	644
2021	515
Thereafter	561
Total	$6,409

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, 2016, 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, 2016 and 2015. 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, 2016 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, 2016 and 2015.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical and commercial 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.

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, Dynavax entered into a Stipulation of Settlement to settle the case entitled In re Dynavax Technologies Securities Litigation. The settlement, which was approved by the U.S. District Court for the Northern District of California on February 6, 2017, provides for a payment of $4.1 million by Dynavax and results in a dismissal and release of all claims against all defendants, including the Company. The settlement was paid for by the Company's insurers. The Company recorded an accrual of $4.1 million reflected in accrued liabilities in the consolidated balance sheets and does not expect any significant additional charges related to this matter. In addition, the Company records anticipated recoveries under existing insurance contracts when recovery is assured. As the settlement will be paid by our insurers, we have recorded a current asset in the amount of $4.1 million reflected in prepaid expenses and other current assets in the consolidated balance sheets.

In February 2017, we tentatively agreed to a settlement for derivative complaints filed in 2013, all of which will be paid by the Company's insurers. The Company recorded an accrual of $0.9 million reflected in accrued liabilities in the consolidated balance sheets and does not expect any significant additional charges related to this matter. In addition, the Company recorded a current asset in the amount of $0.9 million reflected in prepaid expenses and other current assets in the consolidated balance sheets. 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 1.

8. Symphony Dynamo, Inc.

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, 2016.

9. Collaborative Research, Development and License Agreements

AstraZeneca

Pursuant to a research collaboration and license agreement, as amended, with AstraZeneca we discovered and performed initial clinical development of AZD1419, a TLR9 agonist product candidate for the treatment of asthma.

Under the amended agreement we received non-refundable payments of $3.0 million and $5.4 million in 2011 and in 2014, respectively. These payments were deferred and recognized over the estimated period of performance at the time of payment, as subsequently revised.

We have also received payments for development work of $3.0 million, $6.0 million and $8.0 million, in 2011, 2012 and 2014, respectively, which were deferred and recognized as research and development expenses were incurred.

In January 2016, we amended our agreement with AstraZeneca whereby AstraZeneca will conduct the Phase 2a safety and efficacy trial of AZD1419 in patients with asthma that originally was to be conducted by Dynavax. Under the terms of the January 2016 amendment, unused amounts remaining from the $8.0 million payment received in 2014 will be returned to AstraZeneca or offset against future milestone payments that may be earned by us under the agreement, net of amounts we recognized as development work that was performed.

In June 2016, all of our remaining contractual obligations under our agreement with AstraZeneca were completed. As no further performance obligations remain, we revised the estimated period of performance of development work to June 2016 from September 2016, and recognized remaining deferred payments as revenue as of June 30, 2016. The revision of the performance period led to the recognition of an additional $0.8 million in collaboration revenue during 2016.

In November 2016, AstraZeneca initiated the Phase 2a trial of AZD1419 in asthma patients. Upon AstraZeneca's initiation of the Phase 2a trial, Dynavax earned a milestone payment of $7.2 million, which was offset against the $7.4 million in unused development funding previously advanced by AstraZeneca. Dynavax 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 we recognized as a current liability on the accompanying consolidated balance sheets as of December 31, 2016.

Under the terms of the agreement, as amended, we are eligible to receive up to $100 million in additional milestone payments, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on

product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

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,		
	2016	2015	2014
Initial and milestone payment	$7,722	$238	$681
Subsequent payment	1,953	892	2,554
Performance of research activities	103	1,635	2,174
Total	$9,778	$2,765	$5,409

As of December 31, 2016, no deferred revenue from the initial payment, subsequent payment and development funding payments remained. Total deferred revenue from these payments as of December 31, 2015 was $2.7 million.

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.

GlaxoSmithKline ("GSK")

In November 2014 our research and development collaboration and license agreement with GSK expired and we recognized as collaboration revenue $2.5 million, which represented the remaining unrealized portion of the initial $10.0 million payment on signing of the agreement. Revenue from the initial payment from GSK was deferred and was being recognized over the estimated period of performance. Upon expiration of the agreement with GSK in November 2014, we regained global rights to continue the development of DV1179 and other TLR 7/9 inhibitors for all indications. As of December 31, 2016 and 2015 no deferred revenue relating to the initial payment remains.

10. 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.

11. 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, stock awards, warrants and Series B Convertible Preferred Stock are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	December 31,		
	2016	2015	2014
Basic and diluted net loss per share (in thousands, except per share amounts):			
Numerator:			
Net loss	$(112,444)	$(106,794)	$(90,722)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	38,506	32,881	26,289
Basic and diluted net loss per share	$(2.92)	$(3.25)	$(3.45)

Outstanding warrants, stock options, stock awards and Series B Convertible Preferred Stock 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,		
	2016	2015	2014
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Stock options and stock awards	4,673	3,086	1,998
Series B Convertible Preferred Stock (as converted to common stock)	-	-	4,343
Warrants	-	-	1,081
	4,673	3,086	7,422

12. Common Stock and Warrants

Common Stock Outstanding

As of December 31, 2016, there were 38,598,618 shares of our common stock outstanding.

On November 12, 2015, we entered into an At Market Issuance Sales Agreement (the “2015 ATM Agreement”) with Cowen under which we could offer and sell our common stock from time to time up to aggregate sales proceeds of $90 million through Cowen as our sales agent. We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the Agreement. As of December 31, 2016, we have sold no shares of common stock under the 2015 ATM Agreement. For information on sales under the 2015 ATM Agreement subsequent to December 31, 2016, see Note 17.

In July 2015, we completed an underwritten public offering of 5,227,273 shares of our common stock, including 681,818 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 $27.50 per share. The net proceeds to us from this offering were approximately $134.9 million, after deducting the underwriting discount and other estimated offering expenses payable by us.

In June and July 2015, we sold an aggregate of 2,125,439 shares of common stock under an At Market Issuance Sales Agreement (the “2014 ATM Agreement”) with Cowen and Company, LLC (“Cowen”) resulting in net proceeds to us of approximately $49.0 million. The 2014 ATM Agreement terminated in July 2015.

Warrants

As of December 31, 2016 and 2015, no warrants were outstanding. During the year ended December 31, 2015 and 2014, warrants were exercised to purchase an aggregate of approximately 383,000 and 11,000 shares, respectively, of our common stock.

13. Equity Plans and Stock-Based Compensation

Stock Plans

Under the 2004 Stock Incentive Plan ("2004 Plan") options to purchase 173,832 shares of common stock remained outstanding as of December 31, 2016.

Under the 2010 Employment Inducement Award Plan ("Inducement Plan") options to purchase 12,450 shares of common stock remained outstanding as of December 31, 2016.

The 2011 Equity Incentive Plan ("2011 Plan") was approved by the Company's stockholders and adopted in January 2011. On May 31, 2016, 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 3,200,000. The 2011 Plan, as amended, provides for the issuance of up to 8,743,442 shares of our common stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 Plan is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the 2011 Plan have a term of 7 or 10 years unless earlier terminated by the Board of Directors. After the adoption of the 2011 Plan, no additional awards were granted under either the 2004 Plan or the Inducement Plan. As of January 6, 2011, all shares subject to awards outstanding under the 2004 Plan and Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans. As of December 31, 2016, options to purchase 3,787,754 shares of common stock remained outstanding under the 2011 Plan. As of December 31, 2016, there were 3,157,399 shares of common stock reserved for issuance under the 2011 Plan.

Activity under our stock plans is set forth below:

	Shares Underlying Outstanding Options (in thousands)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2015	2,891	$ 23.34		
Options granted	1,414	19.56		
Options exercised	(16)	13.81		
Options cancelled:				
Options forfeited (unvested)	(84)	18.23		
Options cancelled (vested)	(230)	36.64		
Balance at December 31, 2016	3,975	21.38	6.68	$ -
Vested and expected to vest at December 31, 2016	3,951	21.40	6.67	$ -
Exercisable at December 31, 2016	1,836	23.94	5.73	$ -

The total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014 was $0.2 million, $0.4 million and $0.1 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2016, 2015 and 2014 was $12.1 million, $6.9 million and $5.6 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, 2016, and activities during 2016 are summarized as follows:

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2015	195	$ 17.52

Granted	856	$	12.42
Vested	(139)	$	7.24
Forfeited or expired	(213)	$	21.46
Non-vested as of December 31, 2016	699	$	12.12

Stock-based compensation expense related to restricted stock units was approximately $2.4 million for the year ended December 31, 2016. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2016, based on our stock price on that date, was $2.8 million.

The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2016, 2015 and 2014 was, $12.42, $20.05 and $17.92, respectively. The total fair value of restricted stock units vested during the years ended December 31, 2016 and 2015 was $1.0 million and $0.1 million, respectively. No restricted stock units vested during 2014.

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 2011 Plan. As of December 31, 2016, approximately 70,000 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,		
	2016	2015	2014	2016	2015	2014
Weighted-average fair value	$9.54	$13.37	$15.16	$7.86	$9.18	$7.45
Risk-free interest rate	1.4 %	1.7 %	1.8 %	0.6 %	0.4 %	0.2 %
Expected life (in years)	4.9	5.9	5.9	1.2	1.2	1.2
Expected Volatility	0.7	0.7	1.4	0.6	0.6	0.9

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,		
	2016	2015	2014
Employees and directors stock-based compensation expense	$14,126	$9,316	$6,062
Non-employees stock-based compensation expense	-	-	27
Total	$14,126	$9,316	$6,089

	Year Ended December 31,		
	2016	2015	2014
Research and development	$6,742	$4,123	$2,868
General and administrative	$7,384	5,193	3,221
Total	$14,126	$9,316	$6,089

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 2014.

As of December 31, 2016, 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 $22.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.3 years. As of December 31, 2016, the total unrecognized compensation cost related to non-vested stock options not deemed probable of vesting, net of estimated forfeitures, amounted to $0.5 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. On May 31, 2016, stockholders approved an amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance under the plan to 250,000. 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). As of December 31, 2016, employees have acquired 45,547 shares of our common stock under the Purchase Plan and 182,474 shares of our common stock remained available for future purchases under the Purchase Plan.

As of December 31, 2016, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan amounted to $0.5 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years.

14. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. The Company's contribution to the 401(k) Plan approximated $0.2 million for the years ended December 31, 2016 and 2015. No contributions were made during the year ended December 31, 2014.

15. Income Taxes

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

	Year Ended December 31,		
	2016	2015	2014
U.S.	$(114,484)	$(107,450)	$(91,121)
Non U.S.	2,040	656	399
Total	$(112,444)	$(106,794)	$(90,722)

No income tax expense was recorded for the years ended December 31, 2016, 2015 and 2014 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,

	2016	2015	2014
Income tax benefit at federal statutory rate	$(38,183)	$(36,301)	$(30,818)
State tax	(334)	(394)	1,204
Business credits	(1,950)	(2,622)	(1,484)
Deferred compensation charges	3,016	1,481	2,710
Change in valuation allowance	36,751	36,766	28,093
Other	700	1,070	295
Total income tax expense	$-	$-	$-

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

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carry forwards	$249,510	$212,074
Research tax credit carry forwards	29,463	26,285
Accruals and reserves	8,684	9,771
Capitalized research costs	4,457	6,553
Deferred revenue	-	908
Other	1,303	1,375
Total deferred tax assets	293,417	256,966
Less valuation allowance	(293,145)	(256,712)
Net deferred tax assets	272	254
Deferred tax liabilities:		
Fixed Assets	(272)	(254)
Total deferred tax liabilities	(272)	(254)
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 increased by $36.4 million, $36.2 million and $27.8 million during the years ended December 31, 2016, 2015 and 2014, respectively.

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

As of December 31, 2016, we had federal net operating loss carryforwards of approximately $695.9 million, which will expire in the years 2018 through 2036 and federal research and development tax credits of approximately $21.0 million, which expire in the years 2018 through 2036.

As of December 31, 2016, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $178.6 million, which expire in the years 2017 through 2036, and California state research and development tax credits of approximately $15.9 million, which do not expire.

As of December 31, 2016, $1.3 million of net operating loss is attributable to stock-based compensation. As a result of the adoption of ASU 2016-09 we have recognized the net operating losses attributable to stock-based compensation and offset them with a full valuation allowance.

As of December 31, 2016, we had net operating loss carryforwards for foreign income tax purposes of approximately $15.9 million, which do not expire.

The Company asserts ability and intent to postpone remittance of all or part of net investment in Dynavax GmbH (including earnings) indefinitely (i.e., essentially permanently reinvest). As of December 31, 2016, we have cumulative total undistributed earnings for non-U.S. subsidiaries. Deferred income taxes have not been provided on the undistributed earnings of non-U.S. subsidiaries and any deferred tax liabilities, if recognized, are not expected to be significant.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits as of December 31, 2016, 2015 and 2014 is $2.4 million. If recognized, none of the unrecognized tax benefits would affect the effective tax rate. We had no unrecognized tax benefits as of December 31, 2016.

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

Balance at December 31, 2015	$(2,426)
Tax positions related to the current year	
Additions	-
Reductions	-
Tax positions related to the prior year	
Additions	-
Reductions	-
Balance at December 31, 2016	$(2,426)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2016, 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. Due to past equity issuances and changes in ownership of Dynavax common stock, we believe that our ability to use our net operating losses and 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 2016 forward.

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

	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

	Year Ended December 31, 2015			
	Q1	Q2	Q3	Q4
Revenues	$627	$1,550	$1,188	$685
Net loss	$(26,217)	$(23,591)	$(30,124)	$(26,862)
Basic and diluted net loss per share	$(0.97)	$(0.80)	$(0.82)	$(0.70)
Shares used to compute basic and diluted net loss per share	27,065	29,335	36,532	38,429

17. Subsequent Events

As of March 9, 2017 we have received cash of $23.3 million resulting from sales of 5,650,322 shares of our common stock under our 2015 ATM Agreement.

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, our investigational hepatitis B vaccine candidate, through the FDA review and approval process. To achieve these cost reductions, we suspended manufacturing for HEPLISAV-B and reduced our global workforce by 38 percent. We expect to incur restructuring costs related to one-time employee termination benefits, currently estimated to be $3.0 million, which will be primarily paid in cash in the first quarter of 2017.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

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

Based on their evaluation 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, 2016. 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.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Dynavax Technologies Corporation

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2016, 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). Dynavax Technologies Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Dynavax Technologies Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Dynavax Technologies Corporation as of December 31, 2016 and 2015, 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, 2016 of Dynavax Technologies Corporation and our report dated March 13, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 13, 2017

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(c) Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION
None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled “Proposal 1—Elections of Directors,” “Executive Officers,” “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement in connection with the 2017 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, 2016.

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.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES
(a) Documents filed as part of this report:

1. Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

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	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	

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Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
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	10.32	10-Q	August 3, 2007	000-50577	
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	
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	

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
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	May 21, 2015	001-34207	
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	
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	Sales Agreement, dated November 12, 2015, between the Company and Cowen and Company, LLC	10.1	8-K	November 12, 2015	001-34207	
10.19†	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	

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.20+	Employment Agreement, dated March 21, 2013, by and between David Novack and the Company	10.84	10-K	March 10, 2014	001-34207	
10.21+	Employment Agreement, dated July 11, 2013, by and between Robert Janssen, M.D. and the Company	10.85	10-K	March 10, 2014	001-34207	
10.22+	Employment Agreement, dated February 5, 2014, by and between David L. Johnson and the Company	10.86	10-K	March 10, 2014	001-34207	
10.23+	Amended and Restated 2014 Employee Stock Purchase Plan	99.4	S-8	June 1, 2016	333-211747	
10.24+	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	
10.25†	Amendment No. 6 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated December 4, 2014	10.36	10-K	March 5, 2015	001-34207	
10.26	Amendment No. 7 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated January 18, 2016	10.29	10-K	March 8, 2016	001-34207	
10.27+	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	
10.28	Note Purchase Agreement, dated October 26, 2016, by and between Deerfield Partners, L.P., Deerfield International Master Fund, L.P. and the Company					X

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.29	Letter Agreement, dated December 20, 2016, by and between Deerfield Partners, L.P., Deerfield International Master Fund, L.P. and the Company					X
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.

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 13, 2017

By: /s/ MICHAEL OSTRACH
Michael Ostrach

Chief Financial Officer

(Principal Financial Officer)

Date: March 13, 2017

By: /s/ DAVID JOHNSON
David Johnson

Vice President, Chief Accounting Officer

(Principal Accounting Officer)

Date: March 13, 2017

Signature	Title	Date
/s/ EDDIE GRAY Eddie Gray	Chief Executive Officer (Principal Executive Officer)	March 13, 2017
/s/ MICHAEL OSTRACH Michael Ostrach	Chief Financial Officer (Principal Financial Officer)	March 13, 2017
/s/ DAVID JOHNSON David Johnson	Vice President, Chief Accounting Officer (Principal Accounting Officer)	March 13, 2017
/s/ ARNOLD L. ORONSKY, PH.D. Arnold L. Oronsky, Ph.D.	Chairman of the Board	March 13, 2017
/s/ LAURA BREGE Laura Brege	Director	March 13, 2017
/s/ FRANCIS R. CANO, PH.D. Francis R. Cano, Ph.D.	Director	March 13, 2017
/s/ DENNIS A. CARSON, M.D. Dennis A. Carson, M.D.	Director	March 13, 2017
/s/ DANIEL L. KISNER, M.D. Daniel L. Kisner, M.D.	Director	March 13, 2017
/s/ PEGGY V. PHILLIPS Peggy V. Phillips	Director	March 13, 2017
/s/ STANLEY A. PLOTKIN, M.D. Stanley A. Plotkin, M.D.	Director	March 13, 2017
/s/ NATALE S. RICCIARDI Natale S. Ricciardi	Director	March 13, 2017

EXHIBIT INDEX

Exhibit Number	Document	Incorporated by Reference 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	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above					
4.2	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	10.32	10-Q	August 3, 2007	000-50577	

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
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	
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