DYNAVAX TECHNOLOGIES CORP
Form 10-K
March 08, 2016

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

¨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 x 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 x

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 x 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 x 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. x

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 x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

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, 2015 as reported on the NASDAQ Capital Market, was approximately $587,052,465. 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 3, 2016, the registrant had outstanding 38,482,018 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2016 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, 2015.

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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 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,” “fu “intend,” or the negative of these terms or other variations or comparable terminology.

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

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

PART I

ITEM 1. BUSINESS
OVERVIEW

Dynavax Technologies Corporation (“we,” “our,” “us,” “Dynavax” or the “Company”), is a clinical-stage biopharmaceutical company that uses toll-like receptor (“TLR”) biology to discover and develop novel vaccines and therapeutics. Our development programs are focused on vaccines and cancer immunotherapy.

THE COMPANY AND BACKGROUND

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

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

our technology

Toll-like Receptor Immune Modulation Platform

TLRs are a family of transmembrane proteins that play a vital role in innate immunity and subsequent adaptive immunity. These receptors are activated by the binding of certain pathogens and other ligands and their activity is essential to generation of innate immunity. Our research is focused primarily on modulation of endosomal TLRs.

There are several key features of endosomal TLRs that we believe make them promising targets for prophylactic and therapeutic use. They are located within well-defined subsets of immune cells, including dendritic cells, monocytes and B cells. Such targeting may limit the broader immune system stimulation that accompanies many other immunostimulatory agents.

Our product candidates include synthetic oligonucleotides (short segments of DNA) and small molecule agonists and inhibitors of TLRs 7, 8 and 9. The individual sequences and molecules are selected for distinct therapeutic uses based on several factors. Individual molecules are capable of targeting and thereby inhibiting or stimulating an individual TLR or combinations of them and the intensity of stimulation or inhibition can vary greatly. Different molecules that stimulate the same TLR can activate different signaling pathways producing distinct biological responses.

The presence of antigens during TLR stimulation is central to the development of long-term, pathogen-specific adaptive immune responses. Depending on the application, requisite antigens may be co-administered with an agonist or may already be present in the body.

Development Programs

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

Product Candidate	Clinical Indication(s)	Stage of Development
HEPLISAV-B	Hepatitis B prevention	Phase 3
SD-101	Cancer immunotherapy	Phase 1/2
AZD1419	Asthma Disease Modification	Phase 2 Planning
DV281	Cancer immunotherapy	Preclinical
CpG-Nanoparticles	Cancer immunotherapy	Preclinical

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 lead vaccine 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 currently approved vaccines and an adverse event profile similar to an approved hepatitis B vaccine. Based on those data, we submitted a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) in 2012. In 2013 the FDA issued a Complete Response Letter (“CRL”) indicating that it would not approve the BLA primarily because hypothetical risks of the novel adjuvant warranted a larger safety database to assess the possibility of rare autoimmune side effects.

In October 2015 we completed HBV-23, a clinical trial that added more than 5,000 additional subjects to the HEPLISAV-B safety database in order to address the FDA’s need for a larger safety database. HBV-23 was a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV-B compared with GlaxoSmithKline’s (“GSK”) Engerix-B in adults 18 to 70 years of age. HEPLISAV-B subjects received two doses at 0 and 1 month and Engerix-B subjects received three doses at 0, 1 and 6 months.

The primary objectives of HBV-23 were: (1) to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events; and (2) to demonstrate the noninferiority of the peak seroprotection rate induced by HEPLISAV-B compared to Engerix-B in subjects with type 2 diabetes mellitus. HEPLISAV-B subjects were evaluated for safety for one year following the second dose.

Based on preliminary top-line results from HBV-23 released in January 2016, both co-primary endpoints were met. The rates of clinically significant adverse events were consistent with randomization and HEPLISAV-B provided a statistically significant higher rate of seroprotection than Engerix-B in diabetic participants and in all participants as a group.

The total safety database for HEPLISAV-B currently includes 10,038 participants.

At the end of the first quarter of 2016, we intend to submit to FDA our revised BLA and respond to all questions raised in the CRL. We currently expect the submission will be assigned a 6-month Prescription Drug User Fee Act ("PDUFA") review period. If this timing is correct and HEPLISAV-B is approved upon completion of the review period, we expect to launch the product in the fourth quarter of 2016.

HEPLISAV-B Potential Commercial Opportunity

Dynavax has worldwide commercial rights to HEPLISAV-B. We intend to focus our initial commercialization efforts on the U.S. market. 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.

Cancer Immunotherapy

Through our expertise in TLR biology we have designed compounds that stimulate multiple innate mechanisms of tumor killing along with developing immune memory associated with antigens found in tumors. 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 ("PDC").

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 to assess the safety and preliminary efficacy of SD-101 in adults with untreated low-grade B-cell lymphoma. In this multicenter study, SD-101 is administered intratumorally in combination with localized low-dose radiation. In December 2015 we reported on initial clinical results from the dose escalation portion of this study. Tumor regression was observed in both treated and untreated tumors and the combination treatment was well tolerated and resulted in T cell populations consistent with stimulation of anti-tumor immunity.

In October 2015, we initiated a Phase 1/2 multicenter clinical trial to assess the safety and potential efficacy of SD-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with advanced or metastatic melanoma. Following completion of the dose escalation phase, the study is planned to be expanded to enroll patients who have disease that is progressing while receiving an anti-PD-1 therapy or who have baseline characteristics associated with lower rates of response to anti-PD-1 therapy. We also expect that during 2016 our collaborator Merck will begin a Phase 1 trial combining SD-101 and its anti-IL-10 immunomodulator.

One investigator sponsored clinical study assessing SD-101 in combination with an approved checkpoint inhibitor is ongoing and one is planned to begin during 2016.

Our earlier stage cancer immunotherapeutic research programs are focused on development of novel approaches to target TLR9 agonists to the lung or to the liver, delivery of defined tumor antigens in formulations containing TLR9 agonists, and TLR7 and TLR8 agonists.

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. We are currently working with AstraZeneca to design the new trial, which AstraZeneca will fully fund and conduct, and which we expect will begin in the second half of 2016.

Under our September 2006 Research Collaboration and License Agreement with AstraZeneca, a milestone payment is payable to us on initiation of the Phase 2 trial net of any outstanding amounts due to AstraZeneca in respect of unspent payments previously made to us by AstraZeneca to support clinical development. Remaining potential milestone payments to us total approximately $100 million. In addition, we will receive royalties on worldwide sales of any approved products resulting from the collaboration and will have the opportunity to co-promote in the United States.

TLR Inhibitors

We believe there is also strong rationale for the use of TLR inhibitors to treat autoimmune disease. These conditions arise from dysfunction in the innate immune system resulting in the body seeing its own cells and tissues as pathogens and attacking them. Various autoimmune diseases are characterized by over-stimulation of endosomal TLRs.

DV1179 is our lead TLR7/9 inhibitor for autoimmune or inflammatory conditions. Based on preclinical studies, we believe that DV1179 could have potential as a therapeutic candidate in autoimmune and inflammatory indications that do not require systemic bioavailability, including certain skin and liver diseases.

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, 2015, 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 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.

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 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; 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.

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 and inhibitors, 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 in order to ensure supply of product for commercialization. To date, we have manufactured only small quantities of TLR agonists and inhibitors 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 $86.9 million, $84.6 million and $50.9 million for the years ended December 31, 2015, 2014 and 2013, 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, 2015, we had 234 full-time employees, including 137 employees in our headquarters in Berkeley, California and 97 employees in our office and manufacturing facility in Düsseldorf, Germany.

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

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

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

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

In February 2014, we announced our withdrawal of our Marketing Authorization Application (“MAA”) for approval to the EMA. The Day 180 List of Outstanding Issues (“LOI”) provided by the EMA indicated that, based primarily on the Good Clinical Practices (“GCP”) inspection findings, Study HBV-17 was not acceptable without additional assurances regarding the study results and, because some of the findings were related to our overall GCP compliance systems, the other pivotal HEPLISAV-B studies (HBV-10 and HBV-16) were questioned by the EMA. The LOI also noted that the HEPLISAV-B safety database was considered to be too small to rule out a risk of less common serious adverse events, particularly in light of the GCP concerns. We withdrew the application, in part, because the required time

frame for response under the MAA procedure was not long enough to permit the collection of the necessary clinical data.

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

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

Before granting product approval, the FDA must determine that our or our third party 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 take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We are currently undertaking clinical trials of HEPLISAV-B and SD-101 and expect to commence clinical trials for other product candidates in the future. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain Institutional Review Board ("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:

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

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

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

HEPLISAV-B incorporates 1018, a TLR9 agonist CPG oligonucleotide, and most of our research and development programs use similar oligonucleotides. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain oligonucleotides, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. In the past, our clinical trials have identified patients with rare disease adverse events that were reviewed by the FDA in the context of our development efforts and submissions for FDA approval. If adverse event data are

found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

If our lead 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 CDC and ACIP to receive hepatitis B vaccination. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV-B may significantly impact our ability to achieve commercial success in this potential patient population.

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

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

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including 1018 and SD-101, certain antigens, the combination of the oligonucleotide and the antigens, and the formulation, fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development or commercialization efforts.

We have relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing supplier for 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce 1018 at a cost, quantity and quality that are available from our current third-party supplier or at all.

We currently 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. As part of the review of our BLA filing for HEPLISAV-B, the FDA requested additional data regarding our manufacturing process validation program as well as clarifying information on the manufacturing controls and facilities and there can be no assurance that our responses will be sufficient to meet the FDA requirements for GMP manufacturing.

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

HEPLISAV-B, if approved, we may not have the capacity in our existing facility to meet all of our future commercial supply needs. Our current manufacturing capacity could supply up to approximately 2 million doses of rHBsAg annually, and our ability to expand Düsseldorf manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity and stockpile plans, we may experience a shortage in supply of HEPLISAV-B, which could have a material adverse effect on the success of HEPLISAV-B. Likewise, in the event that HEPLISAV-B is not approved, we would have to consider other alternatives for the facility in Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, and time-consuming.

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

We and our third party suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of

our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of 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.

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

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

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

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

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

We have withdrawn our MAA 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 or marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

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

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- 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.

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

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

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors 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. 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.

A consolidated securities class action lawsuit against us is 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 in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials could be time consuming and costly to resolve.

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

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 $699.7 million as of December 31, 2015. 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 (formerly known as Rhein Biotech 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 addition of infrastructure and operations to support further development and regulatory approval of HEPLISAV-B.

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

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

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

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

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

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

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. 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. 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;
- our ability to receive timely regulatory approval for our drug 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;
- 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 litigation has often been brought against a company following a decline in the market price of its securities. We are currently the target of such securities litigation, resulting from the decline in our common stock following the disclosure in 2013 that the FDA would not approve HEPLISAV-B for sale without a significant additional clinical study. We may in the future be the target of additional such litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

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

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

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- 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, 2015, we had 38,445,995 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 Agreement with Cowen, could cause immediate dilution and adversely affect the market price of our common stock. In addition, under the universal shelf registration statement filed by us in November 2015, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings. 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, 2015, we leased approximately 55,200 square feet of laboratory and office space in Berkeley, California under agreements expiring in June 2018. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023.

ITEM 3. LEGAL PROCEEDINGS

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

On June 18, 2013, the first of two substantially similar securities class action complaints was filed in the U.S. District Court for the Northern District of California against the Company and certain of its former executive officers. The second was filed on June 26, 2013. On August 22, 2013, these two complaints and all related actions that subsequently may be filed in, or transferred to, the District Court were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On September 27, 2013, the Court appointed a lead plaintiff and lead counsel. On November 12, 2013, 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 January 10, 2014, defendants filed a motion to dismiss the consolidated complaint.

On March 10, 2014, plaintiffs filed an opposition to the motion to dismiss the consolidated complaint. The opposition introduced a new theory of the case, so defendants permitted plaintiffs to amend their complaint. On April 7, 2014, plaintiffs filed an amended consolidated complaint (“ACC”). The ACC added a new plaintiff and several new defendants, and alleged that, between April 26, 2012 and June 10, 2013, the Company, certain of its executive officers and directors, and entities related to certain of its directors, violated Sections 10(b), 20A, and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder in connection with statements related to our product candidate, HEPLISAV-B. Specifically, the ACC alleged that the Company made fraudulent misrepresentations or omissions regarding the manufacture of HEPLISAV-B and that certain insiders unlawfully profited from such misrepresentations

or omissions. The ACC sought unspecified damages, interest, attorneys' fees, and other costs. On June 6, 2014, defendants filed a motion to dismiss the ACC. On August 8, 2014, plaintiffs filed their Opposition to that motion.

On September 10, 2014, plaintiffs filed the second amended complaint ("SAC") to remove or correct erroneous statements attributed to confidential witnesses. The SAC retains all allegations asserted in the ACC. On October 10, 2014, defendants filed a motion to dismiss the SAC. On November 10, 2014, plaintiffs filed an opposition to the Company's motion to dismiss the SAC. The Company filed its reply in support of the motion on December 1, 2014.

A hearing on the motion to dismiss the SAC occurred on February 20, 2015. The Court granted the motion with respect to some of the alleged misrepresentations and omissions made by the Company or certain named defendants as well as some of the insider trading claims against certain insiders and denied the motion to dismiss with respect to other alleged misrepresentations and omissions and insider trading claims. The Company filed an answer to the SAC on April 6, 2015. Dynavax and the lead plaintiff in the securities class action have participated in mediation.

Additionally, on July 3, 2013, a purported stockholder derivative complaint was filed in the Superior Court of California for the County of Alameda against certain of our 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 the defendants caused or allowed for the dissemination of materially false and misleading statements regarding our product, HEPLISAV-B. Plaintiffs are seeking unspecified monetary damages, including restitution from defendants, attorneys' fees and costs, and other relief.

On August 21, 2013, pursuant to a stipulation between the parties, the State Court stayed the state derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On October 17, 2013, pursuant to a stipulation between the parties, the federal court stayed the federal derivative case pending a decision on the Company's motion to dismiss in the In re Dynavax Technologies Securities Litigation. On May 8, 2015, the parties filed a stipulation to keep the state derivative case stayed until a final resolution in the In re Dynavax Technologies Securities Litigation. On May 15, 2015, the parties also stipulated to keep the federal derivative case stayed until a final resolution in the In re Dynavax Technologies Securities Litigation.

The 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
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
2014		
First Quarter	$20.70	$16.70
Second Quarter	$17.80	$13.00
Third Quarter	$15.90	$13.40
Fourth Quarter	$17.02	$13.70

As of March 3, 2016, there were approximately 80 holders of record of our common stock, as shown on the records of our transfer agent. We believe that our stockholders exceed 14,300 as the number of record holders excludes shares held in "street name" through brokers.

Dividends

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

(a)	(c) Total Number of Shares (or Units) Purchased as of	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that

Period	Total Number of Shares (or Units) Purchased[1] (In thousands)	(b) Average Price Paid per Share (or Unit)	Part of Publicly Announced Plans or Programs	May Yet Be Purchased Under the Plans or Programs
October 1, 2015 to October 31, 2015	-	$ -	-	-
November 1, 2015 to November 30, 2015	-	-	-	-
December 1, 2015 to December 31, 2015	-	-	-	-
Total	-	$ -	-	-

(1) During the 3 months ended December 31, 2015, no securities were purchased by the Company.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, and with the Consolidated Financial Statements and Notes thereto which are included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2015, 2014 and 2013 and the Consolidated Balance Sheets Data as of December 31, 2015 and 2014 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, 2012 and 2011 and the Consolidated Balance Sheets Data as of December 31, 2013, 2012 and 2011 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,				
	2015	2014	2013	2012	2011
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Total revenues	$4,050	$11,032	$11,251	$9,714	$21,614
Operating expenses:					
Research and development	86,943	84,580	50,870	49,146	51,322
General and administrative	22,180	17,377	25,943	28,164	17,570
Unoccupied facility expense	-	386	926	-	-
Amortization of intangible assets	-	-	-	-	299
Total operating expenses	109,123	102,343	77,739	77,310	69,191
Loss from operations	(105,073)	(91,311)	(66,488)	(67,596)	(47,577)
Other income (expense):					
Interest income	205	191	116	291	103
Interest expense	(572)	(35)	-	(2,351)	(1,957)
Other income (expense), net	317	433	(348)	(293)	834
Loss on extinguishment of debt[1]	(1,671)	-	-	-	-
Net loss	(106,794)	(90,722)	(66,720)	(69,949)	(48,597)
Net loss attributable to Dynavax	(106,794)	(90,722)	(66,720)	(69,949)	(48,597)
Preferred stock deemed dividend[2]	-	-	(8,469)	-	-
Net loss allocable to Dynavax common stockholders	$(106,794)	$(90,722)	$(75,189)	$(69,949)	$(48,597)
Basic and diluted net loss per share allocable to Dynavax common stockholders	$(3.25)	$(3.45)	$(3.83)	$(4.10)	$(3.88)
Shares used to compute basic and diluted net loss per share allocable to Dynavax common stockholders	32,881	26,289	19,628	17,047	12,510

(1) In September 2015, we repaid all outstanding amounts under a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules"), at which time our obligations under the Loan Agreement terminated and Hercules released its security interests in all collateral under the 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,				
	2015	2014	2013	2012	2011
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$196,125	$122,652	$189,376	$125,130	$113,961
Working capital	171,161	107,158	176,186	109,173	97,399
Total assets	216,633	138,290	204,622	139,752	134,102
Note payable to Symphony Dynamo Holdings LLC[1]	-	-	-	-	12,810
Long-term debt[2]	-	9,559	-	-	-
Accumulated deficit	(699,727)	(592,933)	(502,211)	(435,491)	(365,542)
Total stockholders' equity	187,079	100,482	186,294	114,826	99,880

(1) Paid in cash on December 31, 2012.
(2) All outstanding amounts under the Loan Agreement with Hercules 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 biopharmaceutical company that uses toll-like receptor ("TLR") biology to discover and develop novel vaccines and therapeutics. Our development programs are focused on vaccines and cancer immunotherapy.

Our vaccine research has focused on the use of TLR9 agonists as novel adjuvants. Our lead vaccine product candidate is HEPLISAV-B™, an investigational adult hepatitis B vaccine, which combines our proprietary TLR9 agonist adjuvant and recombinant hepatitis B surface antigen ("rHBsAg").

At the end of the first quarter of 2016, we intend to submit to the U.S. Food and Drug Administration ("FDA") our revised Biologics License Application ("BLA") and respond to all questions raised in the Complete Response Letter . We currently expect the submission will be assigned a 6-month Prescription Drug User Fee Act ("PDUFA") review period. If this timing is correct and HEPLISAV-B is approved upon completion of the review period, we expect to launch the product in the fourth quarter of 2016.

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. Our SD-101 clinical program is intended to assess the preliminary efficacy of SD-101 in a range of tumors and in combination with a range of treatments. Several Phase 1/2 clinical trials are ongoing or planned for 2016.

Our most advanced inflammatory disease candidate is AZD1419, which is partnered 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. We are currently working with AstraZeneca to design a Phase 2 trial, which AstraZeneca will fully fund and conduct, and is expected to begin in the second half of 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 $699.7 million at December 31, 2015. 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 HEPLISAV-B and our investigational cancer immunotherapeutic product candidate, SD-101, human clinical trials for our other product candidates and additional applications and advancement of our technology. Costs relating to HBV-23 declined following the last subject visit in October 2015, but costs relating to seeking regulatory approval and preparing for the anticipated commercial launch of HEPLISAV-B in the United States, as well as costs related to the ongoing development of SD-101 and our other cancer immunotherapeutic research and development programs, are increasing. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private 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 the HEPLISAV-B program or other 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 entered into prior to January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our 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 cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

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

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

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

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that 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. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under 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, 2015.

Stock-Based Compensation

Stock-based compensation expense for stock options and other stock awards is estimated at the grant date based on the award’s estimated fair value-based measurement and is recognized on a straight-line basis over the award’s requisite service period, assuming appropriate forfeiture rates. Our determination of the fair value-based measurement of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of 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 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. This Accounting Standards Update ("ASU") is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements.

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 periods ending on December 15, 2018 and interim periods therein on a modified retrospective basis. We are currently evaluating the impact this guidance will have on our financial statements.

Results of Operations

Revenues

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

The following is a summary of our revenues (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2014 to 2015		Increase (Decrease) from 2013 to 2014	
Revenues:	2015	2014	2013	$	%	$	%
Collaboration revenue	$2,765	$7,933	$4,929	$(5,168)	(65)%	$3,004	61 %
Grant revenue	683	2,688	5,138	(2,005)	(75)%	(2,450)	(48)%
Service and license revenue	602	411	1,184	191	46 %	(773)	(65)%
Total revenues	$4,050	$11,032	$11,251	$(6,982)	(63)%	$(219)	(2)%

2015 versus 2014

Total revenues for the year ended December 31, 2015, decreased by $7.0 million or 63% as compared to the same period in 2014. Collaboration revenue decreased by $5.2 million 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 by $2.0 million 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 of $0.2 million due to revenue received from manufacturing services performed on behalf of a third party.

2014 versus 2013

Total revenues for the year ended December 31, 2014, decreased by $0.2 million or 2% as compared to the same period in 2013, as the increase in collaboration revenue offset the decrease in grant revenue and service and license revenue. Collaboration revenue for the year ended December 31, 2014, increased by $3.0 million due to a $5.4 million payment received from AstraZeneca in the first quarter of 2014 that is being deferred and recognized over the estimated performance period and recognition of $1.1 million of additional revenue resulting from a revision of the estimated period of performance under the GSK collaboration agreement. Grant revenue for the year ended December 31, 2014, decreased by $2.5 million from the same period in 2013 primarily due to a decrease in revenue recognized from our NIAID contracts for adjuvant development and other programs funded by grants. Service and license revenue for the year ended December 31, 2014, decreased by $0.8 million from the same period in 2013 due to lower royalty revenue received by Dynavax GmbH.

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, 2015, 2014 and 2013, approximately 80%, 80% and 73%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV-B. The remainder of our research and development expense results primarily from earlier-stage programs. The following is a summary of our research and development expense (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2014 to 2015		Increase (Decrease) from 2013 to 2014	
Research and Development:	2015	2014	2013	$	%	$	%
Compensation and related personnel costs	$30,183	$24,352	$20,649	$5,831	24 %	$3,703	18 %
Outside services	45,495	50,923	20,247	(5,428)	(11)%	30,676	152%
Facility costs	7,142	6,437	5,746	705	11 %	691	12 %
Non-cash stock-based compensation	4,123	2,868	4,228	1,255	44 %	(1,360)	(32)%
Total research and development	$86,943	$84,580	$50,870	$2,363	3 %	$33,710	66 %

2015 versus 2014

Research and development expense for the year ended December 31, 2015, increased by $2.4 million, or 3%, as compared to 2014. Compensation and related personnel costs increased by $5.8 million and non-cash stock-based compensation increased by $1.3 million due to an overall increase in employee headcount in preparation for the anticipated approval of HEPLISAV-B and share-based awards granted to employees, respectively. Outside services expense decreased by $5.4 million during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to lower activity related to our HEPLISAV-B clinical trial, HBV-23. Costs relating to HBV-23 are declining following the last subject visit in October 2015, but costs relating to seeking regulatory approval and costs related to the ongoing development of SD-101, are increasing. Facility costs increased by $0.7 million due to an overall increase in employee headcount.

2014 versus 2013

Research and development expense for the year ended December 31, 2014, increased by $33.7 million, or 66%, as compared to 2013. Compensation and related personnel costs increased by $3.7 million due to an overall increase in employee headcount in preparation for the anticipated approval of HEPLISAV-B. Outside services increased by $30.7 million for the year ended December 31, 2014, compared to the same period in 2013 primarily due to the initiation of our HEPLISAV-B clinical trial during 2014. Non-cash stock-based compensation expense decreased by $1.4 million as accelerated vesting of stock options and modifications of stock options related to management continuity and severance agreements was incurred in 2013 and no such expense was incurred in 2014. Facility costs increased by $0.7 million compared to 2013 due to repairs and maintenance of our manufacturing facility.

General and Administrative

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

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

	Year Ended December 31,			Increase (Decrease) from 2014 to 2015		Increase (Decrease) from 2013 to 2014	
General and Administrative:	2015	2014	2013	$	%	$	%
Compensation and related personnel costs	$8,765	$6,637	$10,521	$2,128	32 %	$(3,884)	(37)%
Outside services	5,588	4,325	4,319	1,263	29 %	6	0 %
Legal costs	1,721	2,491	2,361	(770)	(31)%	130	6 %
Facility costs	912	703	630	209	30 %	73	12 %
Non-cash stock-based compensation	5,194	3,221	8,112	1,973	61 %	(4,891)	(60)%
Total general and administrative	$22,180	$17,377	$25,943	$4,803	28 %	$(8,566)	(33)%

2015 versus 2014

General and administrative expenses for the year ended December 31, 2015, increased by $4.8 million, or 28%, compared to the same period in 2014. Compensation and related personnel costs increased by $2.1 million due to an overall increase in employee headcount in preparation for the anticipated commercial launch of HEPLISAV-B in the United States. Non-cash stock-based compensation increased by $2.0 million due to increased annual stock option grants in 2015 and a full year of expense related to 2014 annual option grants recognized in 2015. Outside services increased by $1.3 million due to the hiring of consultants for administrative and commercial development services. Legal costs decreased by $0.8 million as certain ongoing litigation expenses incurred during 2015 were covered under our insurance. Facility costs increased by $0.2 million 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.

2014 versus 2013

General and administrative expenses for the year ended December 31, 2014, decreased by $8.6 million, or 33%, compared to the same period in 2013. Non-cash stock-based compensation decreased by $4.9 million for the year ended December 31, 2014, as the same period in 2013 included accelerated vesting of stock options related to the transition of our former Chief Executive Officer and certain other employees and executive officers. Compensation and related personnel costs decreased by $3.9 million for the year ended December 31, 2014, as the same period in 2013 included severance expense and other one-time compensation costs related to our former Chief Executive Officer and certain other employees and executive officers.

Interest Income, Interest Expense, Other Income (expense) 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 includes interest expense incurred on debt through September 2015 at which time it was repaid. Other income includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment.

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

				Increase	Increase

	Year Ended December 31,			(Decrease) from 2014 to 2015			(Decrease) from 2013 to 2014		
	2015	2014	2013	$	%		$	%	
Interest income	$205	$191	$116	$14	7	%	$ 75	65	%
Interest expense	$(572)	$(35)	$-	$537	1,534	%	$ 35	100	%
Other income (expense), net	$317	$433	$(348)	$(116)	(27)%		$ 781	224	%
Loss on extinguishment of debt	$(1,671)	$-	$-	$1,671	100	%	$ -	-	%

Interest income for the year ended December 31, 2015, remained flat compared to the same period in 2014. Interest income for the year ended December 31, 2014, increased by $0.1 million, or 65%, compared to the same period in 2013 due to higher average marketable securities balance in 2014 as compared to 2013, resulting from the October 2013 common stock and preferred stock offerings which resulted in net proceeds of approximately $80.9 and $44.2 million, respectively.

Interest expense for the year ended December 31, 2015 increased by $0.5 million or 1,534% compared to the same period in 2014 due to interest expense related to the Loan and Security Agreement (the "Loan Agreement") entered into with Hercules Technology Growth Capital, Inc. ("Hercules") in December 2014. Interest expense for the year ended December 31, 2014 increased over the same period in 2013 due to the accretion of interest expense related to the Loan Agreement with Hercules.

Other income (loss) for the year ended December 31, 2015 decreased by $0.1 million or 27%, compared to the same period in 2014 due to 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. Other income (loss) for the year ended December 31, 2014 increased by $0.8 million or 224%, compared to the same period in 2013 due to gain on foreign currency transactions in 2014 related to fluctuations in the value of the Euro compared to the U.S. dollar.

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 loan from Hercules. As of December 31, 2015, we have no debt outstanding.

Liquidity and Capital Resources

As of December 31, 2015, we had $196.1 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. government agency securities and corporate debt securities.

On November 12, 2015, we entered into an At Market Issuance Sales Agreement (the "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. Sales of our common stock through Cowen, if any, will be made by means of ordinary brokers' transactions on The NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and Cowen. Cowen will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the Agreement. No sales of our common stock have taken place under this Agreement as of December 31, 2015.

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 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 from Hercules in September 2015. We also received proceeds of $1.1 million 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 during the year ended December 31, 2015 and 2014, respectively.

During the year ended December 31, 2014, we used $73.7 million of cash for our operations and had 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, accretion and amortization on marketable securities and loss on lease. By comparison, during the year ended December 31, 2013, we used $58.7 million of cash for our operations with a net loss of $66.7 million, of which $15.5 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, accretion and amortization on marketable securities and loss on lease. Cash used in our operations during 2014 increased by $15.1 million.

During the year ended December 31, 2014, cash provided by investing activities was $90.6 million compared to $51.4 million of cash used in investing activities for the year ended December 31, 2013. Cash provided by investing activities during 2014 included $92.3 million of net proceeds of marketable securities versus $49.7 million of net purchases of marketable securities during 2013. Net cash used in the purchases of equipment increased an additional $38 thousand compared to the prior year and totaled $1.7 million and $1.6 million in 2014 and 2013, respectively.

During the year ended December 31, 2014, cash provided by financing activities decreased by $115.5 million, totaling $9.9 million, compared to $125.4 million for the year ended December 31, 2013. Cash provided by financing activities for the year ended December 31, 2014 included net proceeds of $9.6 million drawn down under the Loan Agreement with Hercules. Cash provided by financing activities in 2013 included the sale of 7,957,000 shares of common stock and 43,430 shares of Series B Convertible Preferred Stock in separate underwritten public offerings for net proceeds of $125.1 million. Additionally, proceeds from warrant exercises for the year ended December 31, 2014 increased $0.2 million as compared to the same period in 2013.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of December 31, 2015, and anticipated revenues and expenditures. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B and our investigational cancer immunotherapeutic product candidate, SD-101, human clinical trials for our other product candidates and additional applications and advancement of our technology. Costs relating to HBV-23 R&D expense are declining following the last subject visit in October 2015, and costs relating to seeking regulatory approval and preparing for the anticipated commercial launch of HEPLISAV-B in the United States, as well as costs related to the ongoing development of SD-101, are increasing. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private debt or 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 the HEPLISAV-B program or other development programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2015 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2016	2017-2018	2019-2020	2021 and Thereafter
Operating leases	$7,936	$2,306	$ 3,650	$ 932	$ 1,048
Total	$7,936	$2,306	$ 3,650	$ 932	$ 1,048

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, 2015 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, 2015 and 2014. 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, 2015 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, 2015 and 2014.

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

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of December 31, 2015, under the terms of our agreements, including certain agreements relating to HBV-23, we are obligated to make future payments of approximately $11.2 million through 2016. 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 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 $0.8 million or $1.0 million, respectively.

Due to the short duration and conservative nature of our cash equivalents and marketable securities, as well as our intention to hold the investments to maturity, we do not expect any material loss with respect to our investment portfolio.

Foreign Currency Risk

We have certain investments outside the U.S. for the operations of Dynavax GmbH with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2015 was $2.9 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2015, 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, 2015 and 2014, 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, 2015. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 8, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 8, 2016

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$44,812	$49,511
Marketable securities available-for-sale	151,313	73,141
Accounts receivable	1,394	727
Prepaid expenses and other current assets	2,427	4,058
Total current assets	199,946	127,437
Property and equipment, net	13,804	7,924
Goodwill	2,043	2,277
Restricted cash	609	632
Other assets	231	20
Total assets	$216,633	$138,290
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$3,433	$1,159
Accrued research and development	7,361	6,938
Accrued liabilities	15,337	6,317
Deferred revenues	2,654	5,865
Total current liabilities	28,785	20,279
Deferred revenues, net of current portion	-	6,900
Long term debt	-	9,559
Other long-term liabilities	769	1,070
Total liabilities	29,554	37,808
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock: $0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:		
Series B Convertible Preferred Stock — No shares at December 31, 2015 and 43 shares at December 31, 2014	-	-
Common stock: $0.001 par value; 69,500 shares authorized at December 31, 2015 and 2014, respectively; 38,446 and 26,307 shares issued and outstanding at December 31, 2015 and 2014, respectively	38	26
Additional paid-in capital	889,698	695,058
Accumulated other comprehensive loss	(2,930)	(1,669)
Accumulated deficit	(699,727)	(592,933)
Total stockholders' equity	187,079	100,482
Total liabilities and stockholders' equity	$216,633	$138,290

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Collaboration revenue	$2,765	$7,933	$4,929
Grant revenue	683	2,688	5,138
Service and license revenue	602	411	1,184
Total revenues	4,050	11,032	11,251
Operating expenses:			
Research and development	86,943	84,580	50,870
General and administrative	22,180	17,377	25,943
Unoccupied facility expense	-	386	926
Total operating expenses	109,123	102,343	77,739
Loss from operations	(105,073)	(91,311)	(66,488)
Other income (expense):			
Interest income	205	191	116
Interest expense	(572)	(35)	-
Other income (expense), net	317	433	(348)
Loss on extinguishment of debt	(1,671)	-	-
Net loss	(106,794)	(90,722)	(66,720)
Preferred stock deemed dividend	-	-	(8,469)
Net loss allocable to common stockholders	$(106,794)	$(90,722)	$(75,189)
Net loss per share allocable to common stockholders - basic and diluted	$(3.25)	$(3.45)	$(3.83)
Weighted average shares outstanding used to compute basic and diluted net loss per share allocable to common stockholders	32,881	26,289	19,628

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Net loss	$(106,794)	$(90,722)	$(66,720)
Other comprehensive (loss) income:			
Unrealized gain (loss) on marketable securities available-for-sale	11	32	(76)
Cumulative foreign currency translation adjustments	(1,272)	(1,553)	523
Total other comprehensive (loss) income	(1,261)	(1,521)	447

Total comprehensive loss	$(108,055)	$(92,243)	$(66,273)

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

Common Stock Shares	Common Stock Par Amount	Preferred Stock Par	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'