DYNAVAX TECHNOLOGIES CORP
Form 10-K
February 27, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

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

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2018 as reported on the Nasdaq Capital Market, was approximately $760,000,000. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 22, 2019, the registrant had outstanding 63,996,911 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2019 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, 2018.

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DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our ability to successfully commercialize HEPLISAV-B® and our anticipated level of sales of HEPLISAV-B, our ability to develop and timely achieve regulatory approval for SD-101, DV281 and our other early stage compounds, our business, collaboration and regulatory strategy, changes in our sales organization, our intellectual property position, our product development efforts, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, including additional borrowings under our loan agreement, as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout our document and can be identified by the use of forward-looking language such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “future,” or “intend,” or the negative of these terms or other var or comparable terminology. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

This Annual Report on Form 10-K includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Annual Report on Form 10-K may be trademarks or registered trademarks of their respective owners. References herein to “we,” “our,” “us,” “Dynavax” or the “Company” refer to Dynavax Technologies Corporation and its subsidiary.

PART I

ITEM 1. BUSINESS

OVERVIEW

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

our technology

Toll-like Receptor Immune Modulation Platform

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

Our research has resulted in the identification of proprietary synthetic oligonucleotides (short segments of DNA), that mimic the activity of microbial DNA and selectively activate one of these important receptors, TLR9. These are called CpG oligonucleotides – CpGs for short – referring to the presence of specific nucleotide sequences containing the CG base pair. In addition, we are developing compounds that activate two other important innate receptors, TLR7 and TLR8. These TLR agonists are able to stimulate or modify immune responses as single agents and can synergize with other classes of immunotherapeutic agents. In combination with tumor antigens or vaccines, these TLR agonists can substantially enhance and prolong protective immune responses. Thus, this portfolio of novel and potent activators opens multiple potential opportunities for expanding the scope of cancer immunotherapy, enhancing the efficiency of vaccines and modulating allergic diseases.

Our Strategy

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

HEPLISAV-B

The Company's first commercial product, HEPLISAV-B (Hepatitis B Vaccine, (Recombinant), Adjuvanted), is approved by the FDA for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18

years and older.

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

About Hepatitis B

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

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

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

Worldwide, an estimated 257 million people are living with hepatitis B, including at least 850,000 in the United States, where an estimated 21,000 new infections occur each year.

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

Prevention in Adults with Effective Vaccination

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

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

Protection Against Hepatitis B

The approval of HEPLISAV-B was based on data from three Phase 3 non-inferiority trials of nearly 10,000 adult participants who received HEPLISAV-B. These pivotal studies compared HEPLISAV-B administered in two doses over one month to Engerix-B® administered in three doses over a six-month schedule. Results from HBV-23, the largest Phase 3 trial, which included 6,665 participants, showed that HEPLISAV-B demonstrated a statistically significantly higher rate of protection of 95% compared with 81% for Engerix-B. Across the three clinical trials, the

most common local reaction was injection site pain (23% to 39%). The most common systemic reactions were fatigue (11% to 17%) and headache (8% to 17%).

Commercialization of HEPLISAV-B in the United States

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

We commenced shipments of HEPLISAV-B in January 2018. Currently, total U.S. gross sales for adult hepatitis B vaccines is approximately $300 million annually. We are currently targeting approximately 25% of the total vaccine outlets, which we believe represent approximately 75% of hepatitis B vaccine sales in the U.S., with our field sales force team of approximately 60 people across 10 regions. We plan on converting our independent contractor field sales force team into Dynavax employees in the second quarter of 2019.

In late 2012 the ACIP expanded its recommendation for adults who should be vaccinated against hepatitis B to include people with diabetes mellitus (type 1 and type 2). According to the CDC there are 20 million adults diagnosed with diabetes and another 1.5 million new cases diagnosed each year. This population represents a significant increase in the number of adults recommended for vaccination against hepatitis B in the U.S.

Development Programs

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

Product Candidate	Indication(s)	Stage of Development
Vaccine		
1018 adjuvant	Pertussis	Preclinical
Immuno-oncology		
SD-101 + Pembrolizumab*	Melanoma, anti-PD-1 Naive	Phase 2
SD-101 + Pembrolizumab*	Melanoma, anti-PD-1 Resistant/Refractory	Phase 2
SD-101 + Pembrolizumab*	Head and Neck Squamous Cell Carcinoma	Phase 2
SD-101 + Pembrolizumab	Neoadjuvant breast cancer (I-SPY2)	Phase 2
Inhaled DV281 + Nivolumab	Non-small Cell Lung Cancer	Phase 1
Additional Programs:	Cancer Vaccine	Research
Additional Programs:	TLR7/8 agonists for Oncology	Research

* Clinical collaboration with Merck; Dynavax maintains all commercial rights to SD-101

Immuno-oncology

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

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

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

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

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

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

SD-101 – TLR9 Agonist for intratumoral injection

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

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

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

dose-expansion/dose-finding study are safety and preliminary efficacy.

Results from SD-101 in combination with KEYTRUDA® (pembrolizumab) in Advanced Melanoma Patients Naïve to anti-PD-1/L1 therapy

In October 2018, we reported results from the Phase 1b/2 study on a total of 87 intention to treat (ITT) patients with advanced melanoma naïve to anti-PD-1/L1 therapy. The study compared two different doses of SD-101. In the study, 47 patients received ≤2 mg of SD-101 in up to four lesions and 40 patients received 8 mg in a single lesion. The results showed a

70% (33 out of 47 patients) overall response rate (ORR) in advanced melanoma patients who received the ≤ 2 mg dose of SD-101 and a 48% (19 out of 40 patients) ORR in the group receiving the 8 mg dose of SD-101. The ORR was similar for PD-L1 negative and PD-L1 positive tumors. The combination of SD-101 and KEYTRUDA remained well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms.

Results from SD-101 in combination with KEYTRUDA® (pembrolizumab) in Advanced Melanoma Patients Resistant/ Refractory to anti-PD-1/L1 therapy

In October 2018, we reported results from the Phase 1b/2 study in patients with advanced melanoma resistant/refractory to anti-PD-1/PD-L1 therapy. The results showed a 21% (six out of 29 patients) ORR in patients who received 8 mg in a single lesion. Responses were observed in both SD-101 injected and non-injected lesions. The combination of SD-101 and KEYTRUDA remained well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms. Approximately 25 additional patients are being enrolled to receive 2 mg per injection.

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

Based on the initial results from the combination of SD-101 and KEYTRUDA in melanoma, we expanded the combination study with KEYTRUDA to include a Phase 2 trial in patients with recurrent or metastatic head and neck squamous cell cancers.

In October 2018, we presented data from the Phase 1b/2 clinical trial. The results demonstrated a 27% (six out of 22 patients) ORR who received 8 mg in a single lesion. Responses were observed in both SD-101 injected and non-injected lesions. The combination of SD-101 and KEYTRUDA remained well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms. Approximately 25 additional patients are being enrolled to receive 2 mg per injection.

SD-101 in combination with KEYTRUDA® (pembrolizumab) for Neoadjuvant Breast Cancer (I-SPY2)

In October 2018, we and Quantum Leap Healthcare Collaborative™ (QLHC) announced that the combination of SD-101 and KEYTRUDA (pembrolizumab) will be evaluated in a new randomized, investigational treatment arm for the ongoing I-SPY 2 TRIAL™ for neoadjuvant treatment of locally advanced breast cancer.

The I-SPY 2 TRIAL is a standing Phase 2 randomized, controlled, multicenter study with an innovative Bayesian adaptive design aimed to rapidly screen and identify promising new treatments in specific subgroups of women with newly-diagnosed, high-risk (high likelihood of recurrence), locally-advanced breast cancer (Stage II/III).

DV281 – Inhaled TLR 9 agonist for lung cancer

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

Studies in preclinical animal models of lung cancer show that this direct delivery of DV281 to tumor-bearing lungs results in induction of interferons and cytokines and infiltration of T cells, responses similar to those observed after intratumoral injection of SD-101. Animal models also demonstrate synergy of inhaled DV281 with anti-PD1

antibodies in reducing tumor burden and generating a systemic and durable anti-tumor response. Inhaled DV281, delivered by a nebulizer, entered clinical trials for NSCLC, in combination with anti-PD-1 therapy, in October, 2017. We are conducting the Phase 1 clinical study in subjects with advanced NSCLC to investigate the safety and tolerability of DV281 as monotherapy and in combination with an approved anti-PD-1 inhibitor (nivolumab), and to identify a recommended dose for the expansion part of the study.

AZD1419 for Asthma

AZD1419 is being developed for the treatment of asthma pursuant to a collaboration with AstraZeneca. AZD1419 is designed to change the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms by converting the response from one primarily mediated by type-2 helper T cells to type-1 helper T cells.

In November, 2018, we were informed by our collaborator, AstraZeneca, that initial high-level results from a Phase 2a study indicate AZD1419 treatment was not associated with a statistically significant improvement in the time to loss of asthma control and therefore did not meet the primary endpoint of the study. The treatment appeared to be safe and well tolerated and the study confirmed activation of the TLR9 pathway. The proposed mechanism of action of AZD1419 is distinct from that of the other TLR9 agonists being developed by Dynavax for immuno-oncology and vaccine applications. AstraZeneca is in the process of reviewing the full data before deciding on the next steps for the AZD1419 program.

Vaccine Adjuvants

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

INTELLECTUAL PROPERTY

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

As of December 31, 2018, our intellectual property portfolio included over 30 issued U.S. patents, over 235 issued or granted foreign patents and over 55 additional owned or co-owned 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 two issued patents relating to certain uses of HEPLISAV-B that expire in 2032. We have issued patents expiring in 2023 and covering compositions such as SD-101 and their uses in the U.S. and in several major European and other countries. We anticipate we will be eligible for up to a five-year patent term extension with respect to SD-101. We own or have an exclusive license to U.S. and foreign patents and patent applications pending for each of our other product candidates and/or their uses. At present, it is not known or determinable whether patents will issue from any of these applications or what the specific expiration dates would be for any patents that do issue.

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

the U.S. are effective for:

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

In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The duration of patents varies in accordance with provisions of applicable local law, but typically is 20 years from the filing date. Our patent estate, based on patents existing now and expected by us to issue based on pending applications, will expire on dates ranging from 2018 to 2038.

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

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

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical companies and biotechnology companies, as well as universities and research institutions, may have filed patent applications or may have been granted patents that cover inventions similar to the inventions owned or licensed to us. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use or sell any products. If another party controls patents or patent applications covering our products, we may not be able to obtain the rights we need to those patents or patent applications in order to commercialize our products. One of our competitors, Merck, is an exclusive licensee of a number of broad patents covering HBsAg, a component of HEPLISAV-B. We have a non-exclusive license to those patents controlled by Merck, which was obtained in 2018.

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

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

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our policy is to require each of our commercial partners, employees, consultants and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. These agreements also generally provide that we own all inventions conceived by the individuals in the course of rendering their employment or services to us. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

COMPETITION

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

HEPLISAV-B, a two-dose hepatitis B vaccine, competes directly with conventional three-dose marketed vaccines Engerix-B from GSK as well as Recombivax-HB marketed by Merck. There are also modified schedules of conventional

hepatitis B vaccines for limited age ranges that are approved in the European Union and U.S. In addition, HEPLISAV-B competes against Twinrix, a bivalent 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, cytokines such as anti-IL2, immune stimulation therapies including agonists of TLR, STING and other innate immune recognition receptors; and
- Targeted therapies, such as BRAF inhibitors, MEK inhibitors and BTK inhibitors.
- Oncolytic viral therapies such as IMLYGIC®
- Cancer vaccines such as mRNA for in vivo delivery
- Cell therapies such as autologous tumor infiltrating lymphocytes and CAR-T products

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, Nektar, Pfizer, Amgen, GSK, Regeneron, Novartis, AbbVie and Merck.

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

Many of the entities developing and marketing these competing products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative agreements with large, established companies with access to capital. These entities may also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to or necessary for our programs.

REGULATORY CONSIDERATIONS

Government Regulation

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

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

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;

- completion of extensive pre-clinical laboratory tests and pre-clinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each proposed indication;

- submission to the FDA of a new drug application or a biologics license application, NDA or BLA, depending on the nature of the product after completion of all pivotal clinical trials to demonstrate the safety, purity and potency of the product for the indication for use;
- a determination by the FDA to accept the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with the FDA's current good manufacturing practices regulations for pharmaceuticals, or cGMPs; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the product in the United States.

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

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

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

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

For certain products and indications, the FDA may agree to an abbreviated clinical trial program in order to obtain approval. That is determined on a case-by-case basis and there is no guarantee for any product and/or indication that the FDA will agree to an abbreviated clinical trial program.

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

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

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

Physicians may, in their independent medical judgment, prescribe legally available pharmaceuticals for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding

off-label use. Additionally, a significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, or PDMA, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If our promotional activities, including any promotional activities that a contracted sales force may perform on our behalf, fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require corrective advertising or a recall

or institute fines or civil fines, additional reporting requirements and/or oversight or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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

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

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

The federal criminal and civil false claims laws, including the civil False Claims Act, which prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. In addition, the ACA specified that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The civil

federal False Claims Act has been the basis for numerous enforcement actions and settlements by pharmaceutical and other healthcare companies in connection with various alleged financial relationships with customers. In addition, a number of pharmaceutical manufacturers have reached substantial financial settlements in connection with allegedly causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. Certain marketing practices, including off-label promotion, may also violate false claims laws, as might violations of the federal physician self-referral laws, such as the Stark laws, which prohibit a physician from making a referral to certain designated health services with which the physician or the physician's family member has a financial interest and prohibit submission of a claim for reimbursement pursuant to the prohibited referral. The "qui tam" provisions of the civil False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted similar fraud and abuse statutes

or regulations, including, without limitation, false claims laws analogous to the civil False Claims Act that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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

Healthcare Privacy and Security Laws. We may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which established uniform standards for certain “covered entities” (certain healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA’s privacy and security standards are directly applicable to “business associates” — independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. State laws also govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we are required to comply with international personal data protection laws and regulations, particularly as the result of our operations in Düsseldorf, Germany. Under the European General Data Protection Regulation, or GDPR (EU) 2016/679, personal information about European Union (“E.U.”) citizens can only be transferred from the E.U. to countries with adequate data protection.

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

Government Price Reporting. For those marketed products which are covered in the United States by the Medicaid programs, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including

"covered entities" purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the "additional rebate," a complex calculation which is based, in part, on the rate at which a branded drug price increases over time more than the rate of inflation (based on the CPI-U). This comparison is based on the baseline pricing data for the first full quarter of sales associated with a branded drug's NDA, and baseline data cannot generally be reset, even on transfer of the NDA to another manufacturer. This "additional rebate" calculation can, in

some cases where price increase has been relatively high versus the first quarter of sales of the NDA, result in Medicaid rebates up to 100 percent of a drug's "average manufacturer price" and 340B prices of one penny.

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

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

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs (including a number of proposals pertaining to prescription drugs, specifically), improving quality and/or expanding access. For example, in Massachusetts, the MassHealth program has requested permission from the federal government to use commercial tools, such as a closed formulary, to negotiate more favorable rebate agreements from drug manufactures. There also has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. Such interest has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare

programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product, and on January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump

administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in California, effective January 1, 2019, drug companies must notify insurers and government regulators of certain price increases and provide an explanation of the reasons for such increases.

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

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I

clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, and the Right to Try Act does not invalidate currently existing expanded access programs.

MANUFACTURING

We rely on our facility in Düsseldorf, Germany and third parties to perform the multiple processes involved in manufacturing our product candidates, including the manufacturing of TLR agonists, antigens, and the formulation, fill and

finish of the resultant products. We have relied on a limited number of suppliers to produce products for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. In order to successfully manufacture and commercialize HEPLISAV-B, we have secured long term supply agreements with the key third party suppliers and vendors for supply of product for commercialization. To date, we have manufactured only small quantities of TLR agonists ourselves for development purposes. We currently manufacture the HBsAg for HEPLISAV-B at our Dynavax GmbH facility.

COMMITMENT TO COMPLIANCE AND ENVIRONMENT

We are committed to conducting our business in compliance with all applicable legal and ethical standards. In addition, we are committed to helping to protect the environment.

Our Ethics and Compliance program includes our Code of Business Conduct ("Code"), which sets forth our expectations of all Dynavax employees globally that they conduct their business activities in a legal and ethical manner. The Code can be found on Dynavax.com under the header "Investor Relations" and within that under the header "Corporate Governance and Compliance." We have a Chief Ethics and Compliance Officer, a Compliance Steering Committee and policies, procedures and training addressing specific aspects of our business, including advertising and promotion; engagements with healthcare providers; and regarding our business activities outside the United States to ensure they comply with the U.S. Foreign Corrupt Practices Act and all other applicable anti-corruption laws. We certify on an annual basis to having a comprehensive compliance program that meets the standards set forth under California law. This certification, which sets forth all of the elements of our healthcare compliance program, can be found on our web-site.

We also care about the environment. To that end, the building we are moving into later this year is being designed to be scored as no less than a "Gold" level on the LEED Scorecard as set forth by the United States Green Building Committee. Additionally, the facility is located adjacent to an expansive public transit center, and the Company offers incentives to employees to utilize public transit in order to reduce traffic congestion and pollution. We also allow our employees to telecommute one or more days a week, depending on the nature of their role, which further helps reduce congestion and pollution. In addition, we have an active recycling program. We continue to consider other ways in which we can conduct our business in an environmentally friendly manner.

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, 2018, we had 249 full-time employees, including 169 employees in our headquarters in Berkeley, California and 80 employees in our office and manufacturing facility in Düsseldorf, Germany.

THE COMPANY AND BACKGROUND

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

Our principal executive offices are located at 2929 Seventh Street, Suite 100, Berkeley, California, 94710-2753. Our telephone number is (510) 848-5100. We make available, free of charge on our website located at www.dynavax.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange

Commission. Our code of conduct, audit committee charter, nominating and corporate governance committee charter, compensation committee charter and audit committee complaint procedures are also posted on our website and are each available in print to any stockholder upon request by writing to: 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. The contents of our website are not incorporated by reference into this report.

ITEM 1A. RISK FACTORS

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

Risks Related to our Business and Capital Requirements

HEPLISAV-B has been launched in the United States and there is significant competition in the marketplace. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.

We have established sales, marketing and distribution capabilities and commercialized HEPLISAV-B in the U.S. Successful commercialization of HEPLISAV-B will require significant resources and time and, while Dynavax personnel are experienced with respect to marketing of prescription drug products, because HEPLISAV-B is the company's first marketed product, that the potential uptake of the product in distribution and the timing for growth in sales, if any, may be unpredictable and we may not be successful in commercializing HEPLISAV-B. In particular, successful commercialization of HEPLISAV-B will require that we continue to negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and that we maintain those contractual relationships. There is a risk that we may not complete or maintain all of these important contracts on favorable terms or that in a potentially evolving reimbursement environment our efforts can overcome established competition at favorable pricing.

We anticipate converting our contracted field sales team into full-time Dynavax employees in the second quarter of 2019. The conversion of the field sales team to employees will require additional internal resources, both in the conversion process and for ongoing administrative and logistical support. We have not previously employed an in-house field sales team, and thus have limited experience in overseeing and managing an employed salesforce. In addition, retention of capable sales personnel may be more difficult with a single product offering and we must retain our salesforce in order for HEPLISAV-B to establish a commercial presence.

Moreover, we expect that significant resources will need to be invested in order to successfully market, sell and distribute HEPLISAV-B for use with diabetes patients, one of our targeted patient populations. The Centers for Disease Control and Prevention ("CDC") and the CDC's Advisory Committee on Immunization Practices ("ACIP") recommend that patients with diabetes receive hepatitis B vaccinations and while the potential number of recommended vaccine adult patients is larger than our initial targeted market, we are unable to predict how many of those patients may receive HEPLISAV-B.

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

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

If we are not successful, we may be required to collaborate or partner HEPLISAV-B with a third party pharmaceutical or biotechnology company with existing products. To the extent we collaborate or partner, the financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish

HEPLISAV-B in the market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or in building and maintaining the infrastructure to support commercial operations, we will have difficulty successfully commercializing HEPLISAV-B, which would adversely affect our business and financial condition.

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 or 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, as well as the availability of coverage and adequate reimbursement, from third-party payors, in particular for HEPLISAV-B, where existing products are already marketed. In the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, and we have achieved coverage with most third-party payors. However, there is a risk that some payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include HEPLISAV-B. Thus, there can be no assurance that HEPLISAV-B will achieve and sustain stable pricing and favorable reimbursement. Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market's acceptance of a price for HEPLSIAV-B sufficient to achieve profitability, and future acceptance of such pricing.

Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing, as well as coverage and reimbursement decisions may not allow our future products to compete effectively with existing competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third-party payors to reimburse for our products is uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability, and such unavailability could harm our future prospects and reduce our stock price.

Also, there has been heightened governmental scrutiny recently in the U.S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will

continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In some cases, such legislation and regulations have been designed to encourage importation from other countries and bulk purchasing. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business.

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

In addition to the potential commercial success of HEPLISAV-B, we are dependent on our development stage immune-oncology pipeline of early stage oncology product candidates, and early stage development is inherently risky. Even if we have early indications of success in clinical development, in order to be able to market our products in the U.S., we must obtain approval from the FDA, and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining FDA marketing approval and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The FDA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or proposed post-marketing study, or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations ("CROs"); and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, we received Complete Response Letters from the FDA for HEPLISAV-B in 2013 and 2016 before obtaining approval in November 2017.

In the event that we determine to commercialize HEPLISAV-B outside the United States, such as in Europe, the product is not approved and our opportunity will depend upon our receiving regulatory approval, which can be costly and time consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and/or take other measures which will take time and require that we incur significant additional expense. In addition, there is the risk that we may not receive approval in one or more jurisdictions.

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

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

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

In addition, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for HEPLISAV-B are subject to extensive and ongoing regulatory

requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, GCPs, ICH guidelines, and GLPs. If we are not able to meet and maintain regulatory compliance, we may lose marketing approval and be required to withdraw our product. As noted in the preceding paragraph, withdrawal would have a material adverse effect on our business.

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

We have generated limited revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net losses for the years ended December 31, 2018 and 2017 were $158.9 million and $95.2 million, respectively. As of December 31, 2018, we had an accumulated deficit of $1.1 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S. in addition to our investment in our oncology product candidates, we expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. Our expenses have increased substantially as we established and maintain our HEPLISAV-B commercial infrastructure, including investments in internal infrastructure to support our plans for converting our contracted field sales force to Dynavax employees and investments in manufacturing and supply chain commitments to maintain commercial supply of HEPLISAV-B. The timing for uptake of our product in the U.S. has further increased losses related to commercialization, and the advancement of our oncology pipeline has increased our costs as we conduct more and larger studies to invest in clinical development. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine and pharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

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

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

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

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

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;

- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

Clinical trials for our product candidates are expensive and time consuming, may involve combinations with other agents, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

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

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

Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain Institutional Review Board (“IRB”) or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

Failure by us or our CROs to conduct a clinical study in accordance with GCP standards and other applicable regulatory requirements could result in disqualification of the clinical trial from consideration in support of approval of a potential product.

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

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

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including with respect to our product candidates and those of our partners in combination agent studies:

- deficiencies in the trial design;
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deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;

- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether a product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- a product candidate or combination study may appear to be no more effective than current therapies;

- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- the inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger patient populations, which often occur in later-stage clinical trials, or less favorable clinical outcomes. Moreover, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals.

Third party organizations such as patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by a Data Safety Monitoring Board ("DSMB"), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

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

Most of our programs, including HEPLISAV-B and SD-101, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue or modify many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture HEPLISAV-B and our product candidates. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. With respect to HEPLISAV-B, we have switched to a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture sufficient supply in this presentation.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing HEPLISAV-B and our product candidates, including SD-101 and DV281, certain antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. The FDA approved our pre-filled presentation of HEPLISAV-B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV-B going forward. We have limited experience in manufacturing and supplying this presentation, and there can be no assurance that we can successfully manufacture sufficient quantities of pre-filled syringes in compliance with GMP in order to meet market demand.

We have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing suppliers for 1018 and SD-101, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

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

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

With respect to HEPLISAV-B and our other product candidates in development, we and our third party manufacturers and suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third party manufacturers and suppliers and any manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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

a new supplier is required.

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

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

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

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

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

We withdrew our MAA for HEPLISAV-B in Europe in 2014. We may not be able to provide sufficient data or respond to other comments to our previously filed MAA sufficient to obtain regulatory approval in Europe in a reasonable time period or at all.

Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of our products or limits our marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, such as the FDA approval of HEPLISAV-B in November 2017, and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of HEPLISAV-B and any of our future approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of sufficient reimbursement by third-party payors.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully

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

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

We may need to establish collaborative relationships to obtain domestic and/or international sales, marketing, research and distribution capabilities for those product candidates, including SD-101 and DV281. Failure to obtain a collaborative relationship for those product candidates or HEPLISAV-B in markets outside the U.S. requiring extensive sales efforts, may significantly impair the potential for those products and we may be required to raise additional capital. The process of establishing and maintaining collaborative relationships is difficult and time-consuming, and even if we establish such relationships, they may involve 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.

Additionally, while we have the ability to independently fund certain Phase 3 trials for SD-101, we may need to establish a collaborative relationship with a third party to support certain large Phase 3 studies involving SD-101 in combination with other cancer therapeutics. If we are unable to enter into a collaborative relationship for such a large study, our ability to advance SD-101 to Phase 3 in combination with certain anti-cancer drugs may be significantly harmed, and we may not be able to adequately fund, if at all, such a study in the absence of such a third-party partner. Despite our efforts, we may be unable to secure additional collaborative arrangements that are necessary for us to further develop and commercialize our product candidates, including SD-101 and DV281. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs, and the financial terms upon which collaborators may be willing to enter into such an arrangement cannot be certain.

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

of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors as a result of these disadvantages, we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing therapies to prevent or treat cancer and infectious and inflammatory diseases. For example, HEPLISAV-B competes in the U.S. with established hepatitis B vaccines marketed by Merck and GlaxoSmithKline plc ("GSK") and if approved outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies.

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

Existing and potential competitors may also compete with us for qualified commercial, scientific and management personnel, as well as for technology that would otherwise be advantageous to our business. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel in the near-term, particularly with respect to HEPLISAV-B commercialization. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

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

In February, 2018, we entered into a term loan agreement under which we may borrow up to $175 million. We have borrowed $100 million under the agreement to date. Additional amounts may be borrowed only if we meet certain requirements. The agreement contains covenants that restrict our ability to take various actions, including, among other things, incur additional indebtedness, pay dividends or distributions or make certain investments, create or incur certain liens, transfer, sell, lease or dispose of assets, enter into transactions with affiliates, consummate a merger or sell or other dispose of assets. The agreement also requires us to comply with a daily minimum liquidity covenant and an annual revenue requirement based on the sales of HEPLISAV-B, which is $30 million for fiscal year 2019. The agreement specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default and the acceleration of our repayment obligation at a time when we may not have the cash to comply with that obligation, which could result in a seizure of most of our assets. The restrictions contained in the agreement could also limit our ability to meet capital needs or otherwise restrict our activities and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

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

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

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

As our operations expand, we expect that we will also need to manage additional relationships with various third parties, including sole source suppliers, distributors, wholesalers and hospital customers. Future growth, including managing an in-house field sales team, will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to successfully commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

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

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. Our interactions with physicians and others in a position to prescribe or purchase our products are subject to a legal regime designed to prevent healthcare fraud and abuse and off-label promotion. We also are subject to laws pertaining to transparency of transfers of value to healthcare providers; privacy and data protection; compliance with industry voluntary compliance guidelines; and prohibiting the payment of bribes. Relevant U.S. laws include:

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- federal false claims laws, including the civil False Claims Act, and civil monetary penalty law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education and Reconciliation Act of 2010 (collectively, "PPACA") which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created, among other things, new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their 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; 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; state laws that require drug manufacturers to report information on the pricing of certain drugs; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These

entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the federal civil False Claims Act provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

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

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

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. For example, the PPACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. Some of the provisions of PPACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and on our business.

Other legislative changes have also been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.

In the future, there will likely continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives. In addition, our continued growth to support commercialization may result in difficulties in managing our growth and expanding our operations successfully.

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

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

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

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

The comprehensive tax reform bill passed in 2017 could adversely affect our business and financial condition.

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

in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected.

We use hazardous materials and controlled substances in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials and substances could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste, and controlled substances. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials, substances, and certain waste products. We believe we are currently in compliance with all government permits that are required for the storage, use and

disposal of these materials and controlled substances. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials, or that controlled substances will be accidentally stored or used in violation of relevant federal, state and local requirements. In the event of an accident related to hazardous materials or a violation of requirements pertaining to controlled substances, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations, and laws and regulations pertaining to the storage and use of controlled substances.

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

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

In addition, our systems are potentially vulnerable to data security breaches--whether by employees or others--that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal, state and/or international 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, including but not limited to HIPAA, similar state data protection regulations, and the E.U. General Data Protection Regulation, or GDPR (EU) 2016/679, resulting in significant penalties, increased costs or loss of revenue.

On June 28, 2018, California adopted the California Consumer Privacy Act of 2018 (“CCPA”). The CCPA has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States because it mirrors a number of the key provisions in the GDPR. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. The effective date of the CCPA is January 1, 2020, however, legislators have stated that they intend to propose amendments to the CCPA before it goes into effect. We are continuing to analyze the CCPA in order to determine its applicability and impact to our business.

If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

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

Risks Related to our Intellectual Property

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

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive

licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming and delay or prevent development or commercialization of our product candidates.

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

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.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents for a commercially sufficient term or are otherwise 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 product candidates;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- the success or failure of clinical trials involving our immuno-oncology product candidates and the product candidates of third party collaborators in combination studies;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- changes in government regulations, general economic conditions or industry announcements;
- changes in the structure of healthcare payment systems;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action and shareholder derivative litigation has often been brought against a company following a decline in the market price of its securities. We have in the past been, and we may in the future be, the target of such litigation. Securities and shareholder derivative litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

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

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

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

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

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 as well as new rules implemented by the Securities and Exchange Commission and the Nasdaq Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2018 we had 62,862,478 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

Under our universal shelf registration statement filed by us in August 2017, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our 2017 At Market Sales Agreement with Cowen under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million. As of December 31, 2018, we have $132.8 million remaining under this agreement. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we

are able to obtain additional capital through the sale of equity securities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2018, we lease approximately 40,700 square feet of laboratory and office space in Berkeley, California. In September 2018, we entered into a new lease for 75,662 square feet of laboratory and office space located in Emeryville, California. The Emeryville lease expires in March 2031. In connection with our lease in Emeryville, we entered into a lease termination agreement to terminate the Berkeley lease effective as of the date we vacate the Berkeley premises. We also lease approximately 5,600 square meters of laboratory and office space in Düsseldorf, Germany under lease agreements expiring in March 2023. We believe that our facilities are adequate to meet our requirements for the near term.

ITEM 3. LEGAL PROCEEDINGS

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

On November 18, 2016, two substantially similar securities class action complaints were filed in the U.S. District Court for the Northern District of California against the Company and two of its executive officers, in Soontjens v. Dynavax Technologies Corporation et. al., ("Soontjens") and Shumake v. Dynavax Technologies Corporation et al., ("Shumake"). The Soontjens complaint alleges that between March 10, 2014 and November 11, 2016, the Company and certain of its executive officers violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, in connection with statements related to HEPLISAV-B. The Shumake complaint alleges violations of the same statutes related to the same subject, but between January 7, 2016 and November 11, 2016. The plaintiffs in both actions are seeking an unspecified amount of damages and attorneys' fees and costs. On January 17, 2017, these two actions were consolidated into a single case entitled In re Dynavax Technologies Securities Litigation. On January 31, 2017, the court appointed lead plaintiff and lead counsel. Lead plaintiff filed a consolidated amended complaint on March 17, 2017. Defendants' filed a motion to dismiss the consolidated amended complaint on May 1, 2017. On September 12, 2017, the District Court granted Defendants' motion to dismiss, but gave lead plaintiff an opportunity to amend his complaint. On October 3, 2017, lead plaintiff filed a Second Amended Complaint. Defendants filed a motion to dismiss the Second Amended Complaint on November 3, 2017. A hearing on Defendants' motion to dismiss was held on May 8, 2018. On June 4, 2018, Defendants' motion to dismiss was granted and the case was dismissed with prejudice. On July 3, 2018, lead plaintiff filed a notice of appeal to the U.S. Court of Appeals for the Ninth Circuit. Lead plaintiff's opening appellate brief was due on November 13, 2018. Instead of filing its opening appellate brief, plaintiff filed a motion to voluntarily dismiss its appeal with prejudice and the Ninth Circuit granted that motion on November 16, 2018.

On January 18, 2017, the Company was made aware of a derivative complaint that a purported stockholder of the Company intended to file in the Superior Court of California for the County of Alameda against certain of the Company's current executive officers and directors (the "MacDonald Complaint"). The MacDonald Complaint was apparently filed on February 16, 2017, although the Company was not provided a copy of it until March 15, 2017. Additionally, on January 19, 2017, another purported stockholder of the Company filed a separate derivative complaint in the Superior Court of California for the County of Alameda against the same officers and directors who were named in the MacDonald Complaint (the "Shumake Complaint"). Both complaints generally allege that the defendants caused or allowed the Company to issue materially misleading statements and/or omit material information regarding HEPLISAV-B and the clinical trial related thereto and otherwise mismanaged the clinical trial related to HEPLISAV-B. The complaints seek unspecified monetary damages, including restitution from defendants, corporate governance changes, attorneys' fees and costs, and other relief. Defendants were never served with the Shumake Complaint. On June 23, 2017, the plaintiff voluntarily dismissed the Shumake Complaint without prejudice. Defendants filed a demurrer in the MacDonald case seeking to dismiss the lawsuit on June 19, 2017. On July 26, 2017, pursuant to a stipulation between the parties, the state court stayed the MacDonald case pending the final resolution of the 2016 securities class action, In re Dynavax Technologies Securities Litigation.

On December 1, 2017, the purported stockholder of the Company who filed, and then later voluntarily dismissed, the state court Shumake Complaint, filed a substantially similar purported stockholder derivative complaint in the U.S.

District Court for the Northern District of California (the “Federal Shumake Action”). On February 13, 2018, pursuant to a stipulation between the parties, the District Court stayed the Federal Shumake Action pending the final resolution of the 2016 securities class action, In re Dynavax Technologies Securities Litigation.

Following lead plaintiff’s dismissal of its appeal in the securities class action, the purported stockholders who filed the MacDonald and Shumake actions, voluntarily moved to dismiss their lawsuits, without prejudice. On December 12, 2018, the District Court entered an order dismissing the Federal Shumake action and on December 17, 2018, the Superior Court dismissed the MacDonald lawsuit.

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.

As of February 22, 2019 there were approximately 50 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company ("DTC"). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividends

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

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, and with the Consolidated Financial Statements and Notes thereto which are included elsewhere in this Form 10-K. The Consolidated Statements of Operations Data for the years ended December 31, 2018, 2017 and 2016 and the Consolidated Balance Sheets Data as of December 31, 2018 and 2017 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, 2015 and 2014 and the Consolidated Balance Sheets Data as of December 31, 2016, 2015 and 2014 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,				
	2018	2017	2016	2015	2014
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Product revenue, net	$6,812	$-	$-	$-	$-
Other revenue	1,386	327	11,043	4,050	11,032
Total revenues	8,198	327	11,043	4,050	11,032
Operating expenses:					
Cost of sales - product	10,934	-	-	-	-
Cost of sales - amortization of intangible assets	10,862	1,194	-	-	-
Research and development	74,951	64,988	84,493	86,943	84,580
Selling, general and administrative	64,770	27,367	37,257	22,180	17,377
Restructuring	-	2,783	-	-	-
Unoccupied facility expense	-	-	-	-	386
Total operating expenses	161,517	96,332	121,750	109,123	102,343
Loss from operations	(153,319)	(96,005)	(110,707)	(105,073)	(91,311)
Other income (expense):					
Interest income	3,828	1,337	755	205	191
Interest expense	(9,338)	-	-	(572)	(35)
Other (expense) income, net	(70)	(486)	(2,492)	317	433
Loss on extinguishment of debt	-	-	-	(1,671)	-
Net loss	$(158,899)	$(95,154)	$(112,444)	$(106,794)	$(90,722)
Basic and diluted net loss per share	$(2.55)	$(1.81)	$(2.92)	$(3.25)	$(3.45)
Shares used to compute basic and diluted net loss per share	62,362	52,613	38,506	32,881	26,289

	December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and marketable securities	$145,536	$191,854	$81,415	$196,125	$122,652
Working capital	136,331	179,430	69,563	171,161	107,158
Total assets	210,884	218,785	109,680	216,633	138,290
Long-term debt	100,871	-	-	-	9,559
Accumulated deficit	(1,066,224)	(907,325)	(812,171)	(699,727)	(592,933)
Total stockholders' equity	63,065	199,549	89,201	187,079	100,482

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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 fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation.

Our first commercial product, HEPLISAV-B (Hepatitis B Vaccine (Recombinant), Adjuvanted), is approved by the United States Food and Drug Administration ("FDA") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018.

Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents.

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

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

Product revenue is dependent on our ability to successfully market HEPLISAV-B and our product candidates, if they are approved. Prior to 2018, our revenues consisted of amounts earned from collaborations, grants and fees from services and licenses.

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

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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, stock-based compensation and inventories. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from these estimates under different assumptions or conditions.

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

Revenue Recognition

On January 1, 2018, we adopted Accounting Standards Codification, (“ASC”) 606, Revenue from Contracts with Customers. Adoption of this ASC did not have a material impact on our consolidated financial statements.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell our product to a limited number of wholesalers and specialty distributors in the U.S. (collectively, our “Customers”). Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one-year, there is no financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product

revenue, net in the period of adjustment.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period.

Product Returns: Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory, shelf life of the product and other relevant factors.

Chargebacks: Our Customers subsequently resell our product to healthcare providers. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are determined at the time of resale to the qualified healthcare provider by Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks for units that our Customers have sold to healthcare providers, but for which credits have not been issued.

Trade Discounts and Allowances: We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution Fees: Distribution fees include fees paid to certain Customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

Collaboration Revenue

We enter into collaborative arrangements with other companies. Such arrangements may include promises to customers which, if capable of being distinct, are accounted for as separate performance obligations. For agreements

with multiple performance obligations, we allocate estimated revenue to each performance obligation at contract inception based on the estimated transaction price of each performance obligation. Revenue allocated to each performance obligation is then recognized when we satisfy the performance obligation by transferring control of the promised good or service to the customer.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We estimate our research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of research and development expenses that we report in a particular period.

Stock-Based Compensation

Stock-based compensation expense for restricted stock units and stock options is estimated at the grant date based on the award's estimated fair value and is recognized on a straight-line basis over the award's requisite service period, assuming estimated forfeiture rates. Fair value of restricted stock units is determined at the date of grant using our closing stock price. Our determination of the fair value of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of subjective variables. We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value of our stock options. The Black-Scholes model requires the use of subjective assumptions which determine the fair value of stock options. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value of stock options granted in the future. Changes in the fair value of stock awards could materially impact our operating results.

Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the period of revision.

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. During 2018, we recorded $1.0 million in inventory reserves, which is included in cost of sales – product.

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

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time we began to capitalize inventory costs associated with HEPLISAV-B. In March 2018, we received regulatory approval of the pre-filled syringe ("PFS") presentation of HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. Prior to regulatory

approval of PFS, costs associated with resuming operating activities at the Düsseldorf manufacturing facility were also included in research and development expense. Subsequent to regulatory approval of PFS, costs associated with operating activities at the Düsseldorf facility were included in cost of sales – product, until commercial production resumed in mid-2018 at which time these costs were recorded as raw materials inventory.

Recent Accounting Pronouncements

Accounting Standards Update 2016-02

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) which requires a lessee to recognize a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments, for all leases with a lease term greater than 12 months. In July 2018, the FASB issued ASU 2018-11, Targeted Improvements, which gives the option to apply the transition provisions of ASU 2016-02 at its adoption date instead of at the earliest comparative period presented in its financial statements. Also in July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, which clarifies certain aspects of ASU 2016-02. We will adopt ASU 2016-02 on a modified retrospective basis on its adoption date of January 1, 2019 and elect the available practical expedients upon transition. We will elect the transition method that allows for the application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The new standard will have a material impact on our consolidated balance sheets, but will not have an impact on our consolidated statement of operations. Based on our preliminary analysis, the most significant impact will be the recognition of right-of-use asset and lease liabilities for operating leases ranging approximately from $34 million to $40 million on January 1, 2019. The amount of right-of-use asset and lease liabilities primarily relates to the corporate headquarters operating lease entered into in September 2018.

Results of Operations

Revenues

Recognition of product sales as a result of commercial shipments of HEPLISAV-B commenced in January 2018. Prior to 2018, revenues consisted of amounts earned from collaborations, grants and fees from services and licenses and royalty payments. 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 2017 to 2018		Increase (Decrease) from 2016 to 2017	
Revenues:	2018	2017	2016	$	%	$	%
Product revenue, net	$6,812	$-	$-	$ 6,812	NM	$-	-
Collaboration revenue	1,386	-	9,778	1,386	NM	(9,778)	NM
Grant revenue	-	295	381	(295)	NM	(86)	(23)%
Service and license revenue	-	32	884	(32)	NM	(852)	(96)%
Total revenues	$8,198	$327	$11,043	$ 7,871	NM	$(10,716)	NM

NM = Not meaningful

2018 versus 2017

Product revenue, net, reflects sales of HEPLISAV-B. We commenced commercial shipments of HEPLISAV-B in January 2018 and deployed our field sales force in February 2018. During 2018, quarterly product revenue, net was $0.2 million, $1.3 million, $1.5 million and $3.9 million for the three-month periods ended March 31, June 30, September 30 and December 31, 2018, respectively. Initial efforts during 2018 focused on ensuring market access to enable healthcare providers to purchase HEPLISAV-B including obtaining payor coverage and securing contracts with distributors, group purchasing organizations, physician buying groups and federal government entities. Sales efforts were focused on advancing HEPLISAV-B through the complex approval and procurement processes in large institutional accounts across the country. Based on progress in obtaining approvals during 2018 by several key accounts to make HEPLISAV-B available in their networks and our experience with the protracted time required for implementation and procurement by customers, we expect quarterly sales will increase during 2019 as healthcare providers complete their reviews and operational activities required to switch to the new 2-dose regimen provided by HEPLISAV-B and existing customers repeat orders. Collaboration revenue relates to services performed in 2018 under a collaboration agreement with Serum Institute of India Pvt. Ltd. There was no grant revenue in 2018 as the contract with the National Institutes of Health terminated.

Revenue from product sales is recorded at the net sales price which includes estimates of product returns, chargebacks, discounts, rebates and other fees. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ

from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

2017 versus 2016

No collaboration revenue was recognized in 2017 as all performance obligations under the AstraZeneca agreement were completed in 2016. Service and license revenue decreased in 2017 as no manufacturing services were performed on behalf of third parties in 2017.

Cost of Sales - Product

Cost of sales - product reflects costs of $10.9 million for year ended December 31, 2018. Included in cost of sales - product are inventory reserves and certain formulation, fill, finish and overhead costs for HEPLISAV-B incurred after FDA approval. Cost of sales-product also includes costs at our manufacturing facility in Düsseldorf which were previously included in research and development expense. These charges are a result of costs incurred in 2018 associated with resuming operating activities at the Düsseldorf manufacturing facility after receiving regulatory approval of pre-filled syringes ("PFS") of HEPLISAV-B in late March 2018.

Prior to FDA approval of HEPLISAV-B vials, all costs related to the manufacturing of HEPLISAV-B, that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. Our HEPLISAV-B PFS inventory also includes raw materials costs that were previously expensed to research and development prior to its FDA approval. We expect to use this HEPLISAV-B PFS inventory over approximately the next twelve months.

Excluding the costs associated with resuming operating activities in Düsseldorf, we expect our cost of sales of HEPLISAV-B to increase as a percentage of net sales in future periods as we produce and then sell inventory that reflects the full cost of manufacturing the product. At December 31, 2018 and 2017, inventories, net were $19.0 million and $0.3 million, respectively.

Cost of Sales - Amortization of Intangible Assets

Cost of sales - amortization of intangible assets of $10.9 million and $1.2 million for the year ended December 31, 2018 and 2017, respectively, consists of amortization of the intangible asset recorded as a result of a regulatory milestone and sublicense fees to Coley Pharmaceutical Group, Inc. ("Coley"), Merck, Sharpe & Dohme Corp. ("Merck") and GlaxoSmithKline Biologicals SA ("GSK"), upon or after FDA approval of HEPLISAV-B in November 2017. At December 31, 2018, the intangible assets related to Coley and GSK have been fully-amortized and the intangible asset related to Merck of $11.7 million has an estimated remaining useful life through the patent expiration date in April 2020.

Research and Development

Research and development expense consists, primarily, of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services consist of costs associated with clinical development, preclinical discovery and development, regulatory filings and research, including fees and expenses incurred by contract research organizations, clinical study sites, and other service providers and costs of manufacturing product candidates prior to approval. Prior to FDA approval, we recorded costs of acquiring, developing and manufacturing HEPLISAV-B as research and development expense.

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

	Year Ended December 31,			Increase (Decrease) from 2017 to 2018		Increase (Decrease) from 2016 to 2017	
Research and Development:	2018	2017	2016	$	%	$	%
Compensation and related personnel costs	$30,466	$28,577	$34,333	$1,889	7 %	$(5,756)	(17)%
Outside services	28,213	20,112	32,540	$8,101	40 %	(12,428)	(38)%
Facility costs	6,668	8,472	10,878	$(1,804)	(21)%	(2,406)	(22)%
Non-cash stock-based compensation	9,604	7,827	6,742	$1,777	23 %	1,085	16 %
Total research and development	$74,951	$64,988	$84,493	$9,963	15 %	$(19,505)	(23)%

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2018 versus 2017

Compensation and related personnel costs and non-cash stock-based compensation increased due to an overall increase in headcount to support the ongoing development of SD-101, DV281 and earlier stage oncology programs. Outside services increased, primarily, due to the ongoing development of SD-101.

For the year ended December 31, 2018 and as a result of the regulatory approval of PFS of HEPLISAV-B in late March 2018, costs incurred at our Düsseldorf facility to resume operating activities were charged to cost of sales – product, while costs incurred to manufacture HEPLISAV-B for commercial sale were accounted for as inventory. For the comparative prior year periods, facility costs, which include an overhead allocation of occupancy and related expenses, included full operating costs of our Düsseldorf facility.

2017 versus 2016

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

We expect research and development spending to increase in 2019 in connection with the discovery, development and manufacturing of our product candidates, particularly SD-101 and DV281.

Selling, General and Administrative

Selling, general and administrative expense consists primarily of compensation and related costs for our commercial support personnel, medical education professionals and personnel in executive and other administrative functions including legal, finance and information technology; costs for outside services such as costs for sales and marketing, post-marketing studies of HEPLISAV-B, accounting, commercial development, consulting, business development, investor relations and insurance; legal costs that include corporate and patent-related expenses; allocated facility costs and non-cash stock-based compensation.

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

	Year Ended December 31,			Increase (Decrease) from 2017 to 2018		Increase (Decrease) from 2016 to 2017	
Selling, General and Administrative:	2018	2017	2016	$	%	$	%
Compensation and related personnel costs	$15,993	$8,685	$11,814	$7,308	84 %	$(3,129)	(26)%
Outside services	31,758	7,611	14,400	24,147	317 %	(6,789)	(47)%
Legal costs	2,792	2,777	2,458	15	1 %	319	13 %

Facility costs	2,466	1,204	1,201	1,262	105	%	3	0 %
Non-cash stock-based compensation	11,761	7,090	7,384	4,671	66	%	(294)	(4)%
Total selling, general and administrative	$64,770	$27,367	$37,257	$37,403	137	%	$(9,890)	(27)%

2018 versus 2017

Compensation and related personnel costs and non-cash stock-based compensation increased, primarily, due to an increase in employee headcount to support HEPLISAV-B commercial activities. Outside services increased due to an overall increase in HEPLISAV-B sales, marketing and commercial activities, including full-deployment of a contract sales force, post-marketing studies and consultants for commercial development services. We currently expect to convert from a contract sales force to a sales organization directly employed by us during the second quarter of 2019 and expect the conversion to be approximately cash neutral, with compensation and benefits increasing and a corresponding decrease in outside services related to those activities. Facility costs, which include an overhead allocation and is primarily comprised of occupancy and related expenses, increased due to overall higher facility-related costs and an increase in headcount and costs associated with the new corporate headquarters we expect to occupy in the second quarter of 2019.

2017 versus 2016

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

We expect selling, general and administrative spending to increase in 2019 as we continue to support our commercial activities and incur costs related to the occupancy of the new corporate headquarters.

Restructuring

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

Interest Income, Interest Expense and Other Expense, Net

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense for the year ended December 31, 2018 includes the stated interest and accretion of discount and end of term fee related to our long-term debt agreement entered into in February 2018. Other expense, net includes gains and losses on foreign currency transactions and disposal of property and equipment. In addition, other expense, net for the year ended December 31, 2016 includes expenses related to an unutilized note purchase agreement which was terminated in December 2016.

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

	Year Ended December 31,			Increase (Decrease) from 2017 to 2018		Increase (Decrease) from 2016 to 2017	
	2018	2017	2016	$	%	$	%
Interest income	$3,828	$1,337	$755	$2,491	186 %	$582	77 %

Interest expense	$(9,338)	$-	$-	$9,338	NM	$-	NM
Other expense, net	$(70)	$(486)	$(2,492)	$(416)	(86)%	$(2,006)	(80)%

NM = Not meaningful

2018 versus 2017

Interest income increased primarily due to a higher yield and higher average investment balance. We began incurring interest expense for the $100.0 million we borrowed on February 20, 2018 under a term loan agreement with CRG Servicing LLC. The change in other expense, net is primarily due to foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar.

2017 versus 2016

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

Other expense, net included expense of $5.0 million related to the settlement of securities litigation and the settlement of derivative complaints initiated in 2013. This expense was offset by $5.0 million in other income as the settlements were paid for by our insurers. For more information about our settlements, see Note 9, Commitments and Contingencies, in our Notes to Consolidated Financial Statements.

Liquidity and Capital Resources

As of December 31, 2018, we had $145.5 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, borrowings, government grants and revenues from collaboration agreements to fund our operations. Our funds are currently invested in money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We currently anticipate that our cash, cash equivalents and short-term marketable securities, together with the amounts remaining under our credit facility and anticipated revenues from HEPLISAV-B will be sufficient to fund our operations for at least the next 12 months.

We have borrowed $100.0 million under a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. Subject to our continuing satisfaction of certain market capitalization and other borrowing conditions, we plan to borrow the remaining $75.0 million under the Loan Agreement in the first quarter of 2019. The loans have a maturity date of December 31, 2023, unless prepaid earlier.

At December 31, 2018, $132.8 million of common stock remained available for sale under our At Market Sales Agreement with Cowen and Company, LLC (“ATM Agreement”). Subsequent to December 31, 2018 and through February 22, 2019, we sold 1,078,901 shares of common stock for net proceeds of $11.5 million under the 2017 ATM Agreement.

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

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

2018 versus 2017

During the year ended December 31, 2018, we used $131.3 million of cash for our operations primarily due to our net loss of $158.9 million, of which $39.3 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, amortization of intangible assets and accretion and amortization on marketable securities. During the year ended December 31, 2017, we used $77.5 million of cash for our operations primarily due to a net loss of $95.2 million, of which $18.9 million consisted of non-cash charges such as stock-based compensation, depreciation and amortization, amortization of intangible assets and accretion and amortization on marketable securities. Cash used in our operations during 2018 increased by $53.8 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, 2018, cash provided by investing activities was $55.5 million compared to $108.7 million of cash used in investing activities for the year ended December 31, 2017. Cash provided by investing activities

during the year ended December 31, 2018 included $70.7 million of net proceeds from maturities of marketable securities compared to $108.0 million of net purchases of marketable securities during 2017. During the year ended December 31, 2018, we paid $11.0 million of milestone and sublicense payments to Coley, Merck and GSK. Net cash used in the purchases of property plant and equipment increased by $3.5 million from 2017 to 2018. The increase is, primarily, due to the installation of facility improvements and purchases of laboratory equipment at our corporate headquarters and purchases of manufacturing equipment for our facility in Düsseldorf.

During the year ended December 31, 2018 and 2017, net cash provided by financing activities was $99.1 million and $187.8 million, respectively. During the year ended December 31, 2018, we received net cash proceeds of $99.0 million from the Loan Agreement. During the year ended December 31, 2017, we received net cash proceeds of $105.1 million from issuance of common stock under our ATM Agreements and $80.8 million in net proceeds from issuance of our common stock from our August 2017 underwritten public offering. We received net proceeds of $0.1 million and $1.9 million from exercises of options as well as employee purchases of our common stock under the 2014 Employee Stock Purchase Plan during the year ended December 31, 2018 and 2017, respectively.

2017 versus 2016

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

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

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

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2018 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	Total	2019	2020-2021	2022-2023	2024 and Thereafter
Operating leases	$64,926	$4,839	$10,400	$ 10,164	$ 39,523

Long-term debt obligation	104,808	-	-	104,808	-
Purchase commitments	10,539	10,539	-	-	-
Sublicense agreement	14,000	7,000	7,000		-
Total contractual obligations	$194,273	$22,378	$17,400	$114,972	$ 39,523

We lease our facility in Berkeley, California (“Berkeley Lease”). On September 17, 2018, we entered into an Office/Laboratory Lease (“Lease”), for an aggregate of 75,662 square feet of office and laboratory space located at 5959 Horton Street, Emeryville, California. We are obligated to make lease payments totaling $61.2 million over the Lease term. We are also obligated to pay for operating expenses and taxes. In connection with our execution of the Lease, we entered into a Lease Termination Agreement to terminate the Berkeley Lease effective as of the date we vacate the Berkeley premises.

See Note 9 in the accompanying Notes to the Condensed Consolidated Financial Statements for a description of the Lease and Lease Termination Agreement.

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, 2018 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, 2018 and 2017. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to $1.1 million until such time as our projected cash and cash equivalents will exceed $20 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20 million for a period of 12 consecutive months.

We also lease our facility in Düsseldorf, Germany (“Düsseldorf Lease”) under an operating lease that expires in March 2023. 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, 2018 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, 2018 and 2017.

In February 2018, we entered into a $175.0 million term loan agreement. Principal amount due under the term loan agreement at December 31, 2018 is $101.8 million payable at maturity on December 31, 2023, unless prepaid earlier.

In February 2018, we entered into a sublicense agreement with Merck, Sharpe & Dohme Corp. Under the agreement, we paid the second installment of $7 million in February 2019 and we are required to pay the third installment of $7 million in February 2020.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B and SD-101. To the extent these commitments are non-cancelable, they are reflected in the above table.

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

We also rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators as well as clinical material manufacturers. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

In conjunction with a financing arrangement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”) in November 2009, we agreed to make contingent cash payments to Holdings equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. We have made no payments and have not recorded a liability as of December 31, 2018.

Off-balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK
Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Risk

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The primary objective of our investment activities is to preserve principal and, secondarily, to maximize income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in short-term money market funds, U.S. government agency securities, U.S. Treasuries and corporate debt securities. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. We do not have derivative financial instruments in our investment portfolio. To assess our risk, we calculate that if interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the pro forma change in fair value of our net unrealized loss on investments would be $0.8 million or $1.0 million, respectively.

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

Foreign Currency Risk

We have certain investments outside the U.S. for the operations of Dynavax GmbH with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2018 was $1.9 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2018, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Dynavax Technologies Corporation (the Company) as of December 31, 2018 and 2017, 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, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, 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 February 27, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2002
San Francisco, California
February 27, 2019

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$49,348	$26,584
Marketable securities available-for-sale	96,188	165,270
Accounts and other receivables, net	3,704	854
Inventories, net	19,022	312
Intangible assets, net	-	1,306
Prepaid expenses and other current assets	6,102	3,697
Total current assets	174,364	198,023
Property and equipment, net	17,064	16,619
Intangible assets, net	11,717	-
Goodwill	2,144	2,244
Restricted cash	619	629
Other assets	4,976	1,270
Total assets	$210,884	$218,785
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$5,278	$4,539
Accrued research and development	9,714	4,359
Accrued liabilities	16,041	9,695
Other current liabilities	7,000	-
Total current liabilities	38,033	18,593
Long term debt, net	100,871	-
Other long-term liabilities	8,915	643
Total liabilities	147,819	19,236
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at December 31, 2018 and December 31, 2017; no shares issued and outstanding at December 31, 2018 and December 31, 2017	-	-
Common stock: $0.001 par value; 139,000 shares authorized at December 31, 2018 and 2017; 62,862 and 61,533 shares issued and outstanding at December 31, 2018 and 2017, respectively	63	62
Additional paid-in capital	1,131,241	1,107,693
Accumulated other comprehensive loss	(2,015)	(881)
Accumulated deficit	(1,066,224)	(907,325)
Total stockholders' equity	63,065	199,549
Total liabilities and stockholders' equity	$210,884	$218,785

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product revenue, net	$6,812	$-	$-
Collaboration revenue	1,386	-	9,778
Grant revenue	-	295	381
Service and license revenue	-	32	884
Total revenues	8,198	327	11,043
Operating expenses:			
Cost of sales - product	10,934	-	-
Cost of sales - amortization of intangible assets	10,862	1,194	-
Research and development	74,951	64,988	84,493
Selling, general and administrative	64,770	27,367	37,257
Restructuring	-	2,783	-
Total operating expenses	161,517	96,332	121,750
Loss from operations	(153,319)	(96,005)	(110,707)
Other income (expense):			
Interest income	3,828	1,337	755
Interest expense	(9,338)	-	-
Other expense, net	(70)	(486)	(2,492)
Net loss	$(158,899)	$(95,154)	$(112,444)
Basic and diluted net loss per share	$(2.55)	$(1.81)	$(2.92)
Weighted average shares used to compute basic and diluted net loss per share	62,362	52,613	38,506

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$(158,899)	$(95,154)	$(112,444)
Other comprehensive (loss) income, net of tax:			
Unrealized gain (loss) on marketable securities available-for-sale	12	(83)	(8)
Cumulative foreign currency translation adjustments	(1,146)	2,826	(686)
Total other comprehensive (loss) income	(1,134)	2,743	(694)
Total comprehensive loss	$(160,033)	$(92,411)	$(113,138)

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Additional	Accumulated Other		Total
	Shares	Par Amount	Paid-In Capital	Comprehensive (Loss) Income	Accumulated Deficit	Stockholders' Equity
Balances at December 31, 2015	38,446	$ 38	$889,698	$ (2,930)	$(699,727)	$ 187,079
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	107	1	(84)	-	-	(83)
Issuance of common stock under Employee Stock Purchase Plan	46	-	615	-	-	615
Stock compensation expense	-	-	14,728	-	-	14,728
Total other comprehensive loss	-	-	-	(694)	-	(694)
Net loss	-	-	-	-	(112,444)	(112,444)
Balances at December 31, 2016	38,599	$ 39	$904,957	$ (3,624)	$(812,171)	$ 89,201
Issuance of common stock upon exercise of stock options and restricted stock awards, net	262	-	1,613	-	-	1,613
Issuance of common stock under Employee Stock Purchase Plan	84	-	293	-	-	293
Issuance of common stock, net of issuance costs	22,588	23	185,913	-	-	185,936
Stock compensation expense	-	-	14,917	-	-	14,917
Total other comprehensive income	-	-	-	2,743	-	2,743
Net loss	-	-	-	-	(95,154)	(95,154)
Balances at December 31, 2017	61,533	$ 62	$1,107,693	$ (881)	$(907,325)	$ 199,549
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	1,204	1	(524)	-	-	(523)

Issuance of common stock under						
Employee Stock Purchase Plan	125	-	594	-	-	594
Stock compensation expense	-	-	23,478	-	-	23,478
Total other comprehensive loss	-	-	-	(1,134)	-	(1,134)
Net loss	-	-	-	-	(158,899)	(158,899)
Balances at December 31, 2018	62,862	$ 63	$1,131,241	$ (2,015)	$(1,066,224)	$ 63,065

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2018	2017 (As Adjusted)	2016 (As Adjusted)
Operating activities			
Net loss	$(158,899)	$ (95,154)	$ (112,444)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,621	3,244	2,257
Write-off of assets in progress	-	-	862
Loss (gain) on disposal of property and equipment	98	(10)	91
Accretion of discounts and amortization of premiums on marketable securities	(1,559)	(193)	178
Reversal of deferred rent upon lease amendment	-	(209)	-
Cash-settled portion of stock compensation expense	-	-	602
Stock compensation expense	23,478	14,917	14,126
Cost of sales - amortization of intangible assets	10,862	1,194	-
Non-cash interest expense	2,755	-	-
Changes in operating assets and liabilities:			
Accounts and other receivables	(2,850)	488	52
Inventories, net	(18,710)	(312)	-
Prepaid expenses and other current assets	(2,405)	(1,830)	560
Other assets	(3,706)	(936)	(103)
Accounts payable	3,417	(1,915)	1,181
Accrued liabilities and other long term liabilities	12,597	3,198	(11,759)
Deferred revenues	-	-	(2,654)
Net cash used in operating activities	(131,301)	(77,518)	(107,051)
Investing activities			
Acquisition of technology licenses	(11,000)	-	-
Purchases of marketable securities	(213,804)	(227,672)	(126,754)
Proceeds from maturities of marketable securities	284,457	119,638	220,760
Purchases of property and equipment, net	(4,187)	(669)	(7,757)
Net cash provided by (used in) investing activities	55,466	(108,703)	86,249
Financing activities			
Proceeds from long-term debt, net	99,000	-	-
Proceeds from issuances of common stock, net	-	185,936	-
(Tax withholding) proceeds from exercise of stock options and restricted stock awards, net	(523)	1,613	(84)
Proceeds from Employee Stock Purchase Plan	594	293	615
Net cash provided by financing activities	99,071	187,842	531
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(482)	701	(259)
Net increase (decrease) in cash, cash equivalents and restricted cash	22,754	2,322	(20,530)
Cash, cash equivalents and restricted cash at beginning of year	27,213	24,891	45,421

Cash, cash equivalents and restricted cash at end of year	$49,967	$ 27,213	$ 24,891
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$6,583	$ -	$ -
Accrual for litigation settlement and insurance recovery (Note 9)	$-	$ -	$ 4,975
Release of accrual for litigation settlement and insurance recovery (Note 9)	$-	$ 4,975	$ -
Return of unused development funding to AstraZeneca AB	$-	$ -	$ 7,200
Milestone payment from AstraZeneca AB	$-	$ -	$ 7,200
Non-cash investing and financing activities:			
Disposal of fully depreciated property and equipment	$199	$ 86	$ 2,354
Non-cash acquisition of technology license	$12,773	$ -	$ -

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our first commercial product, HEPLISAV-B (Hepatitis B Vaccine (Recombinant), Adjuvanted), is approved by the United States Food and Drug Administration ("FDA") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology product candidates are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1 safety study. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

Liquidity and Financial Condition

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $145.5 million.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates, discovery research and development and tenant improvements and ongoing occupancy costs at our new corporate headquarters. Until we can generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Adequate financing may not be available to us on acceptable terms, or at all.

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

Use of Estimates

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

Foreign Currency Translation

We consider the local currency to be the functional currency for our international subsidiary, Dynavax GmbH. Accordingly, assets and liabilities denominated in this foreign currency are translated into U.S. dollars using the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing during the year. Currency translation adjustments arising from period to period are charged or credited to accumulated other comprehensive income (loss) in stockholders' equity. For the years ended December 31, 2018, 2017 and 2016, we reported an unrealized (loss) gain of $(1.1) million, $2.8 million and $(0.7) million, respectively. Realized gains and losses resulting from currency transactions are included in other income (expense) in the consolidated statements of operations. For the years ended December 31, 2018, 2017 and 2016, we reported a gain (loss) of $0.3 million, $(0.6) million and $0.2 million, respectively, resulting from currency transactions in our consolidated statements of operations.

Cash, Cash Equivalents and Marketable Securities

We consider all liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty to be cash equivalents. Management determines the appropriate classification of marketable securities at the time of purchase. In accordance with our investment policy, we invest in short-term money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We believe these types of investments are subject to minimal credit and market risk.

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the securities, with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that are subject to concentration of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable.

Our policy is to invest cash in institutional money market funds and marketable securities of the U.S. government and corporate issuers with high credit quality to limit the amount of credit exposure. We currently maintain a portfolio of cash equivalents and marketable securities in a variety of securities, including short-term money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We have not experienced any losses on our cash equivalents and marketable securities.

Our accounts receivable balance consists, primarily, of amounts due from product sales. Accounts receivable are recorded net of reserves for chargebacks, distribution fees, trade discounts and doubtful accounts as described further below. We estimate our allowance for doubtful accounts based on an evaluation of the aging of our receivables. Accounts receivable balances are written off against the allowance when it is probable that the receivable will not be collected. To date, we have not recorded any allowance for doubtful accounts.

Our product candidates will require approval from the FDA and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals may have a material adverse impact on our business and may impact our business in the future. In addition, after the approval of HEPLISAV-B by the FDA, there is still an ongoing risk of adverse events that did not appear during the drug approval process.

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

During the year ended December 31, 2018, 2017 and 2016, 83%, 90% and 92%, respectively, of our revenues were earned in the United States. As of December 31, 2018 and 2017, 24% and 15%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

We have entered into distribution agreements with a limited number of wholesalers and specialty distributors in the U.S. All of our product revenue are to these customers. For the year ended and at December 31, 2018, respectively, our three largest customers represented approximately 68% of our product revenue and 71% of our trade receivable balance.

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. During 2018, we recorded $1.0 million in inventory reserves, which is included in cost of sales – product.

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

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time we began to capitalize inventory costs associated with HEPLISAV-B. In March 2018, we received regulatory approval of the pre-filled syringe (“PFS”) presentation of HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. Prior to regulatory approval of PFS, costs associated with resuming operating activities at the Düsseldorf manufacturing facility were also included in research and development expense. Subsequent to regulatory approval of PFS, costs associated with operating activities at the Düsseldorf facility were included in cost of sales – product, until commercial production resumed in mid-2018 at which time these costs were recorded as raw materials inventory.

Intangible Assets

We record definite-lived intangible assets related to certain capitalized milestone and sublicense payments. After determining that the pattern of future cash flows associated with intangible asset could not be reliably estimated with a high level of precision, these assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. No impairment of intangible assets have been identified during the years presented.

Long-Lived Assets

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

We evaluate the carrying value of long-lived assets, whenever events or changes in business circumstances or our planned use of long-lived assets indicate, based on undiscounted future operating cash flows, that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. When an indicator of impairment exists, undiscounted future operating cash flows of long-lived assets are compared to their respective carrying value. If the carrying value is greater than the undiscounted future operating cash flows of long-lived assets, the long-lived assets are written down to their respective fair values and an impairment loss is recorded. Fair value is determined primarily using the discounted cash flows expected to be generated from the use of assets. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected cash flows. No impairments of tangible assets have been identified during the years presented.

Goodwill

Our goodwill balance relates to our April 2006 acquisition of Dynavax GmbH. Goodwill represents the excess purchase price over the fair value of tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized but is subject to an annual impairment test. In performing its goodwill impairment review, we assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If after assessing the totality of these qualitative factors, we determine that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, we will proceed to perform a test for goodwill impairment. The first step involves comparing the estimated fair value of the related reporting unit against its carrying amount including goodwill. If the carrying amount exceeds the fair value, impairment is calculated and recorded as a charge in the consolidated statements of operations. We determined that we have only one operating segment and there are no components of that operating segment that are deemed to be separate reporting units such that we have one reporting unit for purposes of our goodwill impairment testing. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. No impairments have been identified for the years presented.

Revenue Recognition

On January 1, 2018, we adopted Accounting Standards Codification, (“ASC”) 606, Revenue from Contracts with Customers, using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Under the modified retrospective method, results for the reporting period beginning January 1, 2018 are presented under ASC 606, while the cumulative effect of initially applying the guidance is reflected as an adjustment to the opening balance of retained earnings at January 1, 2018. Adoption of this ASC did not have a material impact on our consolidated financial statements as there were no remaining performance obligations under our license and collaboration agreements as of the adoption date.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations

in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell our product to a limited number of wholesalers and specialty distributors in the U.S. (collectively, our "Customers"). Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one-year, there is no financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. There have been no material adjustments to these estimates for the year ended December 31, 2018.

Product Returns: Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory, shelf life of the product and other relevant factors.

Chargebacks: Our Customers subsequently resell our product to healthcare providers. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are determined at the time of resale to the qualified healthcare provider by

Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks for units that our Customers have sold to healthcare providers, but for which credits have not been issued.

Trade Discounts and Allowances: We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution Fees: Distribution fees include fees paid to certain Customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

Collaboration Revenue

We enter into collaborative arrangements with other companies. Such arrangements may include promises to customers which, if capable of being distinct, are accounted for as separate performance obligations. For agreements with multiple performance obligations, we allocate estimated revenue to each performance obligation at contract inception based on the estimated transaction price of each performance obligation. Revenue allocated to each performance obligation is then recognized when we satisfy the performance obligation by transferring control of the promised good or service to the customer.

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. We estimate research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. There have been no material adjustments to the prior period accrued estimates for clinical trial activities through December 31, 2018.

Stock-Based Compensation

Stock-based compensation expense for restricted stock units and stock options is estimated at the grant date based on the award’s estimated fair value and is recognized on a straight-line basis over the award’s requisite service period, assuming estimated forfeiture rates. Fair value of restricted stock units is determined at the date of grant using the Company’s closing stock price. Our determination of the fair value of stock options on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of subjective variables. We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value-based measurement of our stock options. The Black-Scholes model requires the use of subjective assumptions which determine the fair value-based measurement of stock options. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these input estimates becomes available, we may change or refine our approach of deriving these input estimates. These changes could impact our fair value of stock options granted in the future. Changes in the fair value of stock awards could materially impact our operating results.

Our current estimate of volatility is based on the historical volatility of our stock price. To the extent volatility in our stock price increases in the future, our estimates of the fair value of options granted in the future could increase, thereby increasing stock-based compensation cost recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while giving consideration to options that have not yet completed a full life cycle. Stock-based compensation cost is recognized only for awards ultimately expected to vest. Our estimate of the forfeiture rate is based primarily on our historical experience. To the extent we revise this estimate in the future, our share-based compensation cost could be materially impacted in the period of revision. There have been no material adjustments to these estimates during the years presented.

Income Taxes

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

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

Significant judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

Based on our review, we concluded that it was more likely than not that we would not be able to realize the benefit of our domestic and foreign deferred tax assets in the future. This conclusion was based on historical and projected operating performance, as well as our expectation that our operations will not generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets within the statutory carryover periods. Therefore, we have maintained a full valuation allowance on our deferred tax assets as of December 31, 2018 and 2017. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

On December 22, 2017, President Trump signed U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”), which became effective January 1, 2018. The Tax Act significantly changed the fundamentals of U.S. corporate income taxation by, among many other things, reducing the U.S. federal corporate income tax rate to 21%, converting to a territorial tax system, and creating various income inclusion and expense limitation provisions. Also on December 22, 2017, The Securities and Exchange Commission staff issued Staff Accounting Bulletin (“SAB”) 118 to provide guidance for companies that are not able to complete their accounting for the income tax effects of the Tax Act in the period of enactment. SAB 118 provides for a measurement period of up to one year from the date of enactment. During the measurement period, companies need to reflect adjustments to any provisional amounts if it obtains, prepares or analyzes additional information about facts and circumstances that existed as of the enactment date that, if known, would have affected the income tax effects initially reported as provisional amounts. At December 31, 2018 we have completed our analysis of the Tax Act and there were no material changes or adjustments to the provisional amounts previously recorded.

Restructuring

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

Recent Accounting Pronouncements

Accounting Standards Update 2016-02

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) which requires a lessee to recognize a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments, for all leases with a lease term greater than 12 months. In July 2018, the FASB issued ASU 2018-11, Targeted Improvements, which gives the option to apply the transition provisions of ASU 2016-02 at its adoption date instead of at the earliest comparative period presented in its financial statements. Also in July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, which clarifies certain aspects of ASU 2016-02. We will adopt ASU 2016-02 on a modified retrospective basis on its adoption date of January 1, 2019 and elect the available practical expedients upon transition. We will elect the transition method that allows for the application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The new standard will have a material impact on our consolidated balance sheets, but will not have an impact on our consolidated statement of operations. Based on our preliminary analysis, the most significant impact will be the recognition of right-of-use asset and lease liabilities for operating leases ranging approximately from $34 million to $40 million on January 1, 2019. The amount of right-of-use asset and lease liabilities primarily relates to the corporate headquarters operating lease entered into in September 2018.

Accounting Standards Update 2016-13

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments. The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

Accounting Standards Update 2017-04

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350), which simplifies the test for goodwill impairment by eliminating a previous requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2018-13

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820), that eliminates, adds and modifies certain disclosure requirements of fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2018-15

In August 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other –Internal-Use Software (Subtopic 350-40). This ASU requires a customer in a cloud computing arrangement (i.e. hosting arrangement) that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation

costs to capitalize as assets or expense as incurred. ASC 350-40 requires that certain costs incurred during the application development stage be capitalized and other costs incurred during the preliminary project and post-implementation stages be expensed as incurred. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

Accounting Standards Update 2016-18

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force). This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. The amendment in this update is applied using a retrospective transition method to each period presented. The ASU is effective for annual periods beginning after December 15, 2017. We adopted ASU 2016-18 on January 1, 2018 and have presented comparable prior period cash, cash equivalents and restricted cash balances in the consolidated statements of cash flows reflecting the retrospective impact of this ASU. See Note 4.

3. Fair Value Measurements

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

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

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. There were no transfers between Level 1 and Level 2 during the twelve months ended December 31, 2018 and 2017.

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

As of December 31, 2018, we measured the fair value of our $7.0 million payment to Merck, Sharpe & Dohme Corp. (“Merck”), which is due in the first quarter of 2020, based on Level 3 inputs due to the use of unobservable inputs that cannot be corroborated by observable market data. We estimated the fair value of the liability using a discounted cash flow technique using the effective interest rate on our term loan. The liability had a fair value of $6.3 million as of December 31, 2018.

Recurring Fair Value Measurements

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

	Level 1	Level 2	Level 3	Total
December 31, 2018				
Money market funds	$44,002	$-	$ -	$44,002
U.S. treasuries	-	14,724	-	14,724
U.S. government agency securities	-	42,372	-	42,372
Corporate debt securities	-	41,291	-	41,291
Total	$44,002	$98,387	$ -	$142,389

	Level 1	Level 2	Level 3	Total
December 31, 2017				
Money market funds	$22,543	$-	$ -	$22,543
U.S. treasuries	-	45,534	-	45,534
U.S. government agency securities	-	86,820	-	86,820
Corporate debt securities	-	32,916	-	32,916
Total	$22,543	$165,270	$ -	$187,813

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

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

4. Cash, Cash Equivalents, Restricted Cash and Marketable Securities

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows:

	December 31		
	2018	2017	2016
Cash and cash equivalents	$49,348	$26,584	$24,289
Restricted cash	619	629	602
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$49,967	$27,213	$24,891

Restricted cash balances relate to certificates of deposit issued as collateral to certain letters of credit issued as security to our lease arrangements. See Note 9.

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2018				
Cash and cash equivalents:				
Cash	$ 3,147	$ -	$ -	$3,147
Money market funds	44,002	-	-	44,002
Corporate debt securities	2,199	-	-	2,199
Total cash and cash equivalents	49,348	-	-	49,348
Marketable securities available-for-sale:				
U.S. treasuries	14,732	-	(8)	14,724
U.S. government agency securities	42,416	-	(44)	42,372
Corporate debt securities	39,108	-	(16)	39,092
Total marketable securities available-for-sale	96,256	-	(68)	96,188
Total cash, cash equivalents and marketable securities	$ 145,604	$ -	$ (68)	$145,536
December 31, 2017				
Cash and cash equivalents:				
Cash	$ 4,041	$ -	$ -	$4,041
Money market funds	22,543	-	-	22,543

Total cash and cash equivalents	26,584	-	-	26,584
Marketable securities available-for-sale:				
U.S. treasuries	45,559	-	(25)	45,534
U.S. government agency securities	86,860	-	(40)	86,820
Corporate debt securities	32,931	-	(15)	32,916
Total marketable securities available-for-sale	165,350	-	(80)	165,270
Total cash, cash equivalents and marketable securities	$ 191,934	$ -	$ (80)	$ 191,854

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

.	December 31, 2018	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$96,256	$96,188
Mature after one year through two years	-	-
	$96,256	$96,188

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2018, 2017 and 2016. All of our investments are classified as short-term and available-for-sale, as we consider them available to fund current operations and may not hold our investments until maturity.

5. Inventories, net

The following table presents inventories (in thousands):

	December 31	
	2018	2017
Raw materials	$12,111	$-
Work-in-process	6,562	312
Finished goods	349	-
Total	$19,022	$312

6. Intangible Assets, net

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

	December 31,	
	2018	2017
Intangible assets	$19,773	$2,500
Less accumulated amortization	(8,056)	(1,194)
Total	$11,717	$1,306

For the year ended December 31, 2018, we recorded $10.9 million in cost of sales - amortization of intangible assets which included amortization of $8.1 million, $1.5 million and $1.3 million related to capitalized milestone and sublicense payments to Merck, GlaxoSmithKline Biologicals SA (“GSK”) and Coley Pharmaceutical Group, Inc. (“Coley”), respectively. For the year ended December 31, 2017, we recorded $1.2 million in cost of sales - amortization of intangible assets related to a capitalized milestone payment to Coley. See Note 10. At December 31, 2018, the remaining intangible asset has an estimated remaining useful life of 16 months and will be fully amortized by April 2020. No impairment of intangible assets has been identified during the years presented.

7. Property and Equipment, net

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

	Estimated Useful Life	December 31,	
	(In years)	2018	2017
Manufacturing equipment	5-14	$12,029	$12,104
Lab equipment	5-13	6,938	6,686
Computer equipment	3	5,465	4,760
Furniture and fixtures	3-13	1,809	1,629
Leasehold improvements	1-5	11,367	10,873
Assets in progress		2,605	1,176
		40,213	37,228
Less accumulated depreciation and amortization		(23,149)	(20,609)
Total		$17,064	$16,619

Depreciation and amortization expense on property and equipment was $3.6 million, $3.2 million and $2.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

8. Current Accrued Liabilities and Accrued Research and Development

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

	December 31,	
	2018	2017
Payroll and related expenses	$8,058	$6,180
Legal expenses	151	346
Revenue reserves liability	1,033	-
Third party research expenses	7,819	3,567
Third party development expenses	1,377	522
Other accrued liabilities	7,317	3,439
Total	$25,755	$14,054

9. Commitments and Contingencies

We lease our facilities in Berkeley, California (“Berkeley Lease”), Emeryville, California and Düsseldorf, Germany (“Düsseldorf Lease”).

On September 17, 2018, we entered into an Office/Laboratory Lease (“Lease”) for office and laboratory space located at 5959 Horton Street, Emeryville, California (“Premises”). Under the terms of the Lease, we will lease 75,662 square feet

in the Premises (“Rented Area”) at the rate of $4.75 (“Base Rate”) multiplied by the Rented Area, paid on a monthly basis, starting on the earlier of our commencement of our business operations at the Premises or April 1, 2019 (“Commencement Date”). The Base Rate is subject to scheduled annual increases, and we are also responsible for certain operating expenses and taxes throughout the life of the Lease. In connection with the Lease, we are entitled to a tenant improvement allowance of up to $8.3 million. The Lease has an initial term of 12 years, following the Commencement Date with an option to extend the lease for two successive five-year terms.

In connection with our execution of the Lease, on September 17, 2018, we entered into a Lease Termination Agreement to terminate the Berkeley Lease effective as of the date we vacate the Berkeley premises. The rent payable for the Berkeley Lease is subject to a “hold-over” increase should we not vacate prior to July 31, 2019.

Total net rent expense related to our operating leases for the years ended December 31, 2018, 2017 and 2016, was $4.0 million, $2.4 million and $2.2 million, respectively. Deferred rent was $2.3 million and $0.6 million as of December 31, 2018 and 2017, respectively.

In February 2018, we entered into a $175.0 million term loan agreement. Borrowings under the term loan agreement in the amount of $101.8 million is payable at maturity on December 31, 2023, unless earlier prepaid. See Note 11.

In February 2018, we entered into a sublicense agreement with Merck. Under the agreement, we are required to make future payments of $7.0 million each in both February 2019 and February 2020. See Note 10.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B and SD-101. To the extent these commitments are non-cancelable, they are reflected in the table below.

Future payments under the term loan agreement, sublicense agreement, minimum payments under the non-cancelable portion of our operating leases and non-cancelable purchase commitments at December 31, 2018, are as follows (in thousands):

Year ending December 31,	
2019	$22,378
2020	12,256
2021	5,144
2022	5,212
2023	109,760
Thereafter	39,523
Total	$194,273

During 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of $0.4 million. The letter of credit remained outstanding as of December 31, 2018, 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, 2018 and 2017. 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, 2018 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, 2018 and 2017.

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

We also rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

In conjunction with a financing arrangement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC ("Holdings") in November 2009, we agreed to make contingent cash payments to Holdings equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. We have made no payments and have not recorded a liability as of December 31, 2018 and 2017.

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

On September 7, 2016, we entered into a Stipulation of Settlement to settle the case entitled In re Dynavax Technologies Securities Litigation filed in 2013. The settlement, which was approved by the U.S. District Court for the Northern District of California on February 6, 2017, provided for a payment of $4.1 million by us and results in a dismissal and release of all claims against all defendants, including us. The settlement was paid by our insurers in February 2017.

On October 24, 2017, we entered into a Stipulation of Settlement to settle the derivative case filed in 2013. The settlement provided for a payment of $0.9 million by us and results in a dismissal and release of all claims against all defendants, including us. The settlement was paid by our insurers in November 2017.

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

10. Collaborative Research, Development and License Agreements

AstraZeneca

Pursuant to a research collaboration and license agreement with AstraZeneca AB (AstraZeneca”), as amended, we discovered and performed initial clinical development of AZD1419, a TLR9 agonist product candidate for the treatment of asthma. In June 2016, all of our remaining performance obligations under our agreement with AstraZeneca were completed and we recognized collaboration revenue of $9.8 million. In November 2018, we were informed by AstraZeneca that initial results from the Phase 2a study indicate AZD1419 treatment did not meet the primary endpoint of the study. AstraZeneca is reviewing the full data before deciding on the next steps for the AZD1419 program.

Serum Institute of India Pvt. Ltd.

In June 2017, we entered into an agreement to provide Serum Institute of India Pvt. Ltd. (“SIIPL”) with technical support. In consideration, SIIPL agreed to pay us at an agreed upon hourly rate for services and reimburse certain out-of-pocket expenses. In addition, we have rights to commercialization of certain potential products manufactured at the SIIPL facility. During the fourth quarter of 2018, we recognized collaboration revenue for services performed through December 31, 2018.

Merck, Sharp & Dohme Corp.

In February 2018, we entered into a Sublicense Agreement (the “Sublicense Agreement”) with Merck. The Sublicense Agreement grants us, under certain non-exclusive U.S. patent rights controlled by Merck which relate to recombinant production of hepatitis B surface antigen, the right to manufacture, use, offer for sale, sell and import HEPLISAV-B

in the United States and includes the right to grant further sublicenses. Under the terms of the Sublicense Agreement, we are obligated to pay $21.0 million in three installments. The first installment of $7.0 million was paid in February 2018 and the remaining two payments of $7.0 million each are due in the first quarter of each of 2019 and 2020. The payments in 2019 and 2020 are classified on the condensed consolidated balance sheets as other current liabilities and other long-term liabilities, respectively. In February 2018, we recorded $19.8 million as an intangible asset. At December 31, 2018, the intangible asset, net balance was $11.7 million. See Note 6. The agreement continues in effect through April 2020, at which time the license becomes perpetual, irrevocable, fully paid-up and royalty free.

GlaxoSmithKline Biologicals SA

On July 12, 2018, we entered into a sublicense agreement with GSK. The GSK sublicense agreement grants us, under certain non-exclusive U.S. patent rights controlled by GSK, the right to manufacture, use, offer to sell, sell and import HEPLISAV-B in the United States and includes the right to grant further sublicenses. In consideration, we paid a $1.5 million license fee to GSK in July 2018 and recorded this payment as an intangible asset. At December 31, 2018, the intangible asset has been fully amortized. See Note 6. In addition, we were obligated to pay GSK, royalties of 13% of net sales of HEPLISAV-B from December 1, 2017 through July 31, 2018. For the year ended December 31, 2018, we recorded $0.2 million of royalties in cost of sales – product in the condensed consolidated statements of operations.

Coley Pharmaceutical Group, Inc.

In June 2007, we entered into a license agreement with Coley, under which Coley granted us a non-exclusive, royalty bearing license to patents, with the right to grant sublicenses for HEPLISAV-B (the “Coley Agreement). We met one of the regulatory milestones upon FDA approval of HEPLISAV-B in November 2017 and paid $2.5 million in January 2018 to Coley which was recorded as an intangible asset on the consolidated balance sheets. See Note 6. The Coley Agreement terminated in February 2018, at which time the license became a perpetual, irrevocable, fully paid-up and royalty free license. As of December 31, 2018, the $2.5 million intangible asset has been fully amortized.

11. Long-Term Debt

Long-Term Debt

On February 20, 2018, we entered into a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. The Loan Agreement provides for a $175.0 million term loan facility, $100.0 million of which was borrowed at closing (“Initial Term Loan”) and, subject to the satisfaction of certain market capitalization and other borrowing conditions, up to an additional $75.0 million is available for borrowing at our option on or before July 17, 2019 (together with the Initial Term Loan, the “Term Loans”). Net proceeds from the Initial Term Loan were $99.0 million. The Term Loans under the Loan Agreement bear interest at a rate equal to 9.5% per annum. At December 31, 2018, the effective interest rate was 10.1%. At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through December 31, 2018, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $101.8 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. The Term Loans and paid-in-kind interest will be entirely payable at maturity.

The obligations under the Loan Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the Company and any future subsidiary guarantors, except for certain customary excluded property, and (ii) all of the capital stock owned by the Company and such future subsidiary guarantors (limited, in the case of the stock of certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, to 65% of the capital stock of such subsidiaries, subject to certain exceptions). The obligations under the Loan Agreement will be guaranteed by each of the Company’s future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions). The Loan Agreement contains customary covenants and requires us to comply with a $15.0 million daily minimum combined cash and investment balance covenant and an annual revenue requirement starting in 2019 for sales of HEPLISAV-B.

The Term Loans may be prepaid by us at any time. If the Term Loans are prepaid prior to the second anniversary of the initial borrowing date, we are subject to a repayment premium of up to 7.0% of the principal amount prepaid, depending on the date of prepayment.

We recorded $8.8 million of interest expense related to the Initial Term Loan during the year ended December 31, 2018.

Note Purchase Agreement

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

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

12. Revenue Recognition

Our source of product revenue for the year ended December 31, 2018, consists of sales of HEPLISAV-B in the U.S. The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the year ended December 31, 2018 (in thousands):

	Chargebacks, discounts and other fees	Returns	Total
Balance at December 31, 2017	$ -	$ -	$-
Provision related to current period sales	4,012	570	4,582
Credit or payments made during the period	(2,276)	(1)	(2,277)
Balance at December 31, 2018	$ 1,736	$ 569	$2,305

At December 31, 2018, reserves for chargebacks and discounts totaling $1.3 million were recorded as reductions of accounts receivable while the remaining reserves balances totaling $1.0 million were recorded as accrued liabilities in the condensed consolidated balance sheets.

13. Net Loss Per Share

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

	December 31,		
	2018	2017	2016
Basic and diluted net loss per share (in thousands, except per share amounts):			
Numerator:			
Net loss	$(158,899)	$(95,154)	$(112,444)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	62,362	52,613	38,506
Basic and diluted net loss per share	$(2.55)	$(1.81)	$(2.92)

Outstanding stock options and stock awards were excluded from the calculation of net loss per share allocable to common stockholders as the effect of their inclusion would have been anti-dilutive.

	December 31,		
	2018	2017	2016
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Stock options and stock awards	7,344	5,981	4,673

14. Common Stock
Common Stock Outstanding

As of December 31, 2018, there were 62,862,478 shares of our common stock outstanding.

On November 3, 2017, we entered into an At Market Sales Agreement ("2017 ATM Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion, shares of our common stock having an aggregate offering price up to $150 million through Cowen as our sales agent. We pay Cowen a commission of up to 3% of the gross sales proceeds of any common stock sold through Cowen under the 2017 ATM Agreement. For the year ended December 31, 2017, we received net cash proceeds of $16.9 million resulting from sales of 840,774 shares of our common stock. As of December 31, 2018, we have $132.8 million remaining under the 2017 ATM Agreement. Subsequent to December 31, 2018 and through February 22, 2019, we sold 1,078,901 shares of common stock for net proceeds of $11.5 million under the 2017 ATM Agreement.

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

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

15. Equity Plans and Stock-Based Compensation
Stock Plans

On May 31, 2018, our stockholders approved the 2018 Equity Incentive Plan (the "2018 EIP"). The 2018 EIP is intended to be the successor to the Dynavax Technologies Corporation 2011 Equity Incentive Plan (the "2011 EIP"). The aggregate number of shares of our common stock that may be issued under the 2018 EIP (subject to adjustment for certain changes in capitalization) is comprised of the sum of (i) 5,000,000 newly reserved shares of common stock, (ii) 140,250 unallocated shares of common stock remaining available for grant under the 2011 EIP as of May 31, 2018, and (iii) 7,477,619 shares subject to outstanding stock awards granted under the 2011 EIP and the Dynavax Technologies Corporation 2017 Inducement Award Plan that may become available from time to time as set forth in the 2018 EIP. The 2018 EIP provides for the issuance of up to 12,617,869 shares of our common stock to employees of the Company. The 2018 EIP is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the 2018 EIP have a term of 7 years unless earlier terminated by the Board of Directors. As of December 31, 2018, options to purchase 5,750,404 shares of common stock remained outstanding under the 2018 EIP. As of December 31, 2018, there were 4,810,112 shares of common stock reserved for issuance under the 2018 EIP.

Activity under our stock plans is set forth below:

	Shares Underlying Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value

	(in thousands)			(years)	(in thousands)
Balance at December 31, 2017	3,555	$	19.56		
Options granted	2,503		16.30		
Options exercised	(42	)	11.80		
Options cancelled:					
Options forfeited (unvested)	(178	)	14.29		
Options expired (vested)	(88	)	29.58		
Balance at December 31, 2018	5,750	$	18.20	5.47	$ 651
Vested and expected to vest at December 31, 2018	5,534	$	18.28	5.44	$ 644
Exercisable at December 31, 2018	2,975	$	19.90	4.87	$ 466

The total intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $0.2 million, $0.9 million and $0.2 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2018, 2017 and 2016 was $8.1 million, $13.0 million and $12.1 million, respectively.

Our non-vested stock awards are comprised of restricted stock units granted with performance and time-based vesting criteria. A summary of the status of non-vested restricted stock units as of December 31, 2018, and activities during 2018 are summarized as follows:

	Number of Shares	Weighted-Average Grant-Date Fair Value
	(In thousands)	
Non-vested as of December 31, 2017	2,443	$ 6.01
Granted	458	15.98
Vested	(1,219)	5.86
Forfeited	(88)	9.07
Non-vested as of December 31, 2018	1,594	$ 8.82

Stock-based compensation expense related to restricted stock units was approximately $8.4 million for the year ended December 31, 2018. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2018, based on our stock price on that date, was $14.6 million.

The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2018, 2017 and 2016 was, $15.98, $5.34 and $12.42, respectively. The total fair value of restricted stock units vested during the years ended December 31, 2018, 2017 and 2016 was $19.4 million, $1.2 million and $1.0 million, respectively.

Stock-Based Compensation

Under our stock-based compensation plans, option awards generally vest over a three-year or four-year period contingent upon continuous service and unless exercised, expire seven or ten years from the date of grant (or earlier upon termination of continuous service). The Company has also granted performance-based equity awards to certain of our employees. As of December 31, 2018, approximately 151,000 shares underlying stock options and approximately 12,500 restricted stock unit awards with performance-based vesting criteria were outstanding. Vesting criteria for 5,000 of the awards with performance-based vesting criteria were not probable as of December 31, 2018. We recognized stock-based compensation expense for awards with performance-based vesting criteria during the years ended December 31, 2018, 2017 and 2016 of $1.9 million, $0.3 million and $0.5 million, respectively.

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

Stock Options

	Year Ended December 31,			Employee Stock Purchase Plan Year Ended December 31,		
	2018	2017	2016	2018	2017	2016
Weighted-average fair value	$10.75	$8.27	$9.54	$8.30	$3.05	$7.86
Risk-free interest rate	2.5 %	1.9 %	1.4 %	2.4 %	1.0 %	0.6 %
Expected life (in years)	4.2	4.5	4.9	1.3	1.2	1.2
Expected Volatility	0.8	0.9	0.7	1.1	1.0	0.6

Expected volatility is based on historical volatility of our stock price. The expected life of options granted is estimated based on historical option exercise and employee termination data. Our senior management, who hold a majority of the options outstanding, and other employees were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. Forfeiture estimates are based on historical employee turnover. The dividend yield is zero percent for all years and is based on our history and expectation of dividend payouts.

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

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

	Year Ended December 31,		
	2018	2017	2016
Employees and directors stock-based compensation expense	$23,478	$14,917	$14,126

	Year Ended December 31,		
	2018	2017	2016
Research and development	$9,604	$7,827	$6,742
Selling, general and administrative	11,761	7,090	7,384
Cost of sales - product	1,354	-	-
Inventory	759	-	-
Total	$23,478	$14,917	$14,126

In addition, the cash-settled portion of stock compensation expense was $0.6 million for the year ended December 31, 2016. No cash-settled portion of stock compensation expense was incurred during 2017 or 2018.

As of December 31, 2018, the total unrecognized compensation cost related to non-vested stock options and awards deemed probable of vesting, including all stock options with time-based vesting, net of estimated forfeitures, amounted to $26.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.9 years. Additionally, as of December 31, 2018, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $0.3 million.

Employee Stock Purchase Plan

The Amended and Restated 2014 Employee Stock Purchase Plan (the “Purchase Plan”) provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. On May 31, 2018, our stockholders approved an amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance by 600,000 shares. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the sixteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fifteenth day in February or August). For the year ended December 31, 2018, employees have acquired 125,193 shares of our common stock under the Purchase Plan and 573,034 shares of our common stock remained available for future purchases under the Purchase Plan.

As of December 31, 2018, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan amounted to $0.5 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.6 years.

16. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. The Company's contribution to the 401(k) Plan was approximately $0.2 million for each of the years ended December 31, 2018, 2017 and 2016.

17. Restructuring

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

18. Income Taxes

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

	Year Ended December 31,		
	2018	2017	2016
U.S.	$(160,032)	$(95,898)	$(114,484)
Non U.S.	1,133	744	2,040
Total	$(158,899)	$(95,154)	$(112,444)

No income tax expense was recorded for the years ended December 31, 2018, 2017 and 2016 due to our full valuation allowance position. The difference between the consolidated income tax benefit and the amount computed by applying the federal statutory income tax rate to the consolidated loss before income taxes was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Income tax benefit at federal statutory rate	$(33,366)	$(32,352)	$(38,183)
State tax	(5,591)	(4,482)	(334)
Business credits	(3,065)	(1,960)	(1,950)
Deferred compensation charges	(1,165)	3,823	3,016
Change in valuation allowance	43,134	(109,165)	36,751
Rate change	-	86,943	-
Net operating loss and tax credit limitation	-	56,962	-
Other	53	231	700
Total income tax expense	$-	$-	$-

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carry forwards	$178,730	$146,300
Research tax credit carry forwards	34,064	29,658
Accruals and reserves	10,137	6,551
Capitalized research costs	943	1,422
Other	1,147	731
Total deferred tax assets	225,021	184,662
Less valuation allowance	(224,746)	(184,388)
Net deferred tax assets	275	274
Deferred tax liabilities:		
Fixed assets	(275)	(274)

Total deferred tax liabilities	(275)	(274)
Net deferred tax assets	$-	$-

The tax benefit of net operating losses, temporary differences and credit carryforwards is required to be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance. The valuation allowance increased by $40.4 million during the year ended December 31, 2018 due to an increase in our deferred tax assets and decreased by $108.8 million during the year ended December 31, 2017 primarily as a result of the reduction in our deferred tax assets resulting from the decrease in the U.S. federal statutory tax rate.

On December 22, 2017, President Trump signed U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which became effective January 1, 2018. The Tax Act significantly changes the fundamentals of U.S. corporate income taxation by, among many other things, reducing the U.S. federal corporate income tax rate to 21%, converting to a territorial tax system, and creating various income inclusion and expense limitation provisions.

Also on December 22, 2017, The Securities and Exchange Commission staff issued Staff Accounting Bulletin ("SAB") 118 to provide guidance for companies that are not able to complete their accounting for the income tax effects of the Tax Act in the period of enactment. SAB 118 provides for a measurement period of up to one year from the date of enactment. During the measurement period, companies need to reflect adjustments to any provisional amounts if it obtains, prepares or analyzes additional information about facts and circumstances that existed as of the enactment date that, if known, would have affected the income tax effects initially reported as provisional amounts.

At December 31, 2018 we have completed our analysis of the Tax Act. The Act included a re-measurement of our net U.S. deferred tax assets reducing the U.S. federal corporate rate to 21%, which was offset by a valuation allowance. During 2018, this amount was finalized and no additional adjustment was required due to the change in corporate tax rate.

The one-time transition tax is based on our total post-1986 earnings and profits that we previously deferred from U.S. income taxes. In 2017 we recorded a provisional amount for our one-time transition tax liability for our foreign subsidiaries. In 2018 the transition tax calculation was completed. The transition tax that we calculated resulted in an immaterial reduction income from the provisional amount recorded in 2017.

Also effective for 2018 is a new Global Intangible Low-Taxed Income inclusion ("GILTI"). The GILTI income inclusion did not have a material impact on our 2018 current loss or valuation allowance position. We elected to account for GILTI as a period cost in the year the income or tax is incurred.

As of December 31, 2018, we had federal net operating loss carryforwards of approximately $771.8 million, which will begin to expire in the year 2019 and federal research and development tax credits of approximately $19.9 million, which expire in the years 2019 through 2038.

As of December 31, 2018, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $229.0 million, which expire in the years 2019 through 2038, and California state research and development tax credits of approximately $19.1 million, which do not expire.

As of December 31, 2018, we had net operating loss carryforwards for foreign income tax purposes of approximately $11.9 million, which do not expire.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits was $1.2 million as of each of the years ended December 31, 2018 and 2017. If recognized, none of the unrecognized tax benefits would affect the effective tax rate.

The following table summarizes the activity related to our unrecognized tax benefits:

Balance at December 31, 2017	$(1,229)
Tax positions related to the current year	
Additions	-
Reductions	-

Tax positions related to the prior year	
Additions	-
Reductions	-
Balance at December 31, 2018	$(1,229)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2018, there was no interest related to unrecognized tax benefits. No amounts of penalties related to unrecognized tax benefits were recognized in the provision for income taxes. We do not anticipate any significant change within 12 months of this reporting date of its uncertain tax positions.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event there is a change in ownership, as defined, the annual utilization of such carryforwards could be limited. Based on an analysis under Section 382 of the Internal Revenue Code, completed through December 31, 2018, we experienced ownership changes in 2008, 2009 and 2012 which limit the future use of its pre-change federal net operating loss carryforwards and federal research and development tax credits. We excluded these federal net operating loss carryforwards and federal research and development tax credits that will expire as a result of the annual limitations in the deferred tax assets as of December 31, 2018. A limitation calculation has not been performed with respect to the California net operating loss carryforwards and research and development tax credits and we believe that our ability to use these California net operating loss carryforwards and research and development tax credits in the future may be limited.

We are subject to income tax examinations for U.S. federal and state income taxes from 1999 forward. We are subject to tax examination in Germany from 2017 forward and in India from 2018 forward.

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

	Year Ended December 31, 2018			
	Q1	Q2	Q3	Q4
Total revenues	$165	$1,254	$1,461	$5,318
Net loss	$(38,958)	$(39,444)	$(40,528)	$(39,969)
Basic and diluted net loss per share	$(0.63)	$(0.63)	$(0.65)	$(0.64)
Shares used to compute basic and diluted net loss per share	61,744	62,346	62,650	62,694

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

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

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued a report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control— Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Dynavax Technologies Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, 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, 2018 and the related notes of the Company and our report dated February 27, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

San Francisco, California

February 27, 2019

(c) Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION
None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled “Proposal 1—Elections of Directors,” “Executive Officers,” “Corporate Governance” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement in connection with the 2019 Annual Meeting of Stockholders (the “Proxy Statement”) which will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2018.

We have adopted the Dynavax Code of Business Conduct and Ethics (“Code of Conduct”), a code of ethics that applies to our employees, including our Chief Executive Officer, Chief Financial Officer and to our non-employee directors. The Code of Conduct is publicly available on our website under the Investors and Media section at www.dynavax.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this report. If any substantive amendments are made to the Code of Conduct or any waiver granted, including any implicit waiver, from a provision of the Code of Conduct to our Chief Executive Officer or Chief Financial Officer, we will disclose the nature of such amendment or waiver on that website or in a report on Form 8-K. We will provide a written copy of the Dynavax Code of Conduct to anyone without charge, upon request written to Dynavax, Attention: Corporate Secretary, 2929 Seventh Street, Suite 100, Berkeley, CA 94710-2753, (510) 848-5100.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this Item is incorporated by reference to the section entitled “Executive Compensation Program,” “Director Compensation,” “Compensation Discussion and Analysis,” “Report of the Compensation Committee of the Board of Directors on Executive Compensation,” “Outstanding Equity Awards at Fiscal Year End” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement.

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

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

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

Information required by this Item is incorporated by reference to the sections entitled “Certain Transactions With” and “Independence of the Board of Directors” in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

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

1. Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

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

(b) Exhibits

Exhibit		Incorporated by Reference				
		Exhibit				
Number	Document	Number	Filing	Filing Date	File No.	Filed Herewith
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	
3.3	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	3.3	8-K	November 6, 2008	000-50577	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	

Exhibit		Incorporated by Reference Exhibit				Filed
Number	Document	Number	Filing	Filing Date	File No.	Herewith
3.9	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 and 3.9 above					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
10.01†	Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB	10.30	10-Q	November 3, 2006	000-50577	
10.02	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and the Company	10.2	10-Q	November 3, 2017	001-34207	
10.03†	Amendment No. 2 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated February 3, 2009	10.40	10-Q	April 30, 2009	001-34207	
10.04	Amended and Restated Purchase Option Agreement, dated November 9, 2009, between the Company and Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.	10.47	10-K	March 16, 2010	001-34207	
10.05	Amendment No. 3 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between the Company and AstraZeneca AB, dated September 30, 2010	10.54	8-K	October 4, 2010	001-34207	
10.6	Lease, dated January 7, 2004, between the Company and 2929 Seventh Street, LLC	10.17	S-1/A	January 16, 2004	333-109965	
10.7	First Amendment to Lease, dated as of May 21, 2004, between the Company and 2929 Seventh Street, LLC	10.55	8-K	October 13, 2010	001-34207	

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.8	Second Amendment to Lease, dated as of October 12, 2010, between the Company and 2929 Seventh Street, LLC	10.56	8-K	October 13, 2010	001-34207	
10.9+	Amended and Restated 2011 Equity Incentive Plan	99.1	S-8	June 1, 2016	333-211747	
10.10+	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan	99.2	S-8	January 6, 2011	333-171552	
10.11+	Form of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan	99.3	S-8	January 6, 2011	333-171552	
10.12	Third Amendment to Lease, dated as of April 1, 2011, between the Company and 2929 Seventh Street, LLC	10.65	10-Q	August 3, 2011	001-34207	
10.13†	Amendment No. 4 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated September 23, 2011	10.67	10-K	March 12, 2012	001-34207	
10.14	Fourth Amendment to Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC	10.72	10-K	March 8, 2013	001-34207	
10.15	Lease, dated as of December 14, 2012, between the Company and 2929 Seventh Street, LLC	10.73	10-K	March 8, 2013	001-34207	
10.16+	Employment Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company	10.78	8-K	May 3, 2013	001-34207	
10.17+	Management Continuity and Severance Agreement, dated as of April 3, 2013, by and between Eddie Gray and the Company	10.79	8-K	May 3, 2013	001-34207	

Exhibit Number	Document	Incorporated by Reference Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
10.18†	Amendment No. 5 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, dated January 7, 2014	10.88	10-K	March 10, 2014	001-34207	
10.19+	Employment Agreement, dated March 6, 2013, by and between David Novack and the Company	10.84	10-K	March 10, 2014	001-34207	
10.20+	Employment Agreement, dated July 12, 2013, by and between Robert Janssen, M.D. and the Company	10.85	10-K	March 10, 2014	001-34207	
10.21+	Employment Agreement, dated February 4, 2014, by and between David L. Johnson and the Company	10.86	10-K	March 10, 2014	001-34207	
10.22+	Amended and Restated 2014 Employee Stock Purchase Plan	99.4	S-8	June 1, 2016	333-211747	
10.23†	Amendment No. 6 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, effective as of December 8, 2014	10.36	10-K	March 5, 2015	001-34207	
10.24	Amendment No. 7 to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and the Company, effective as of January 13, 2016	10.29	10-K	March 8, 2016	001-34207	
10.25+	Form of Amended and Restated Management Continuity and Severance Agreement between the Company and certain of its executive officers	10.1	8-K	April 19, 2016	001-34207	
10.26	Fifth Amendment to Lease, dated as of May 15, 2017, between the Company and 2929 Seventh Street, LLC	10.2	10-Q	August 7, 2017	001-34207	
10.27	Sales Agreement, dated November 3, 2017, between the Company and Cowen and Company, LLC	10.1	10-Q	November 3, 2017	001-34207	

Exhibit		Incorporated by Reference Exhibit				Filed
Number	Document	Number	Filing	Filing Date	File No.	Herewith
10.28†	2017 Inducement Award Plan	10.1	8-K	November 30, 2017	001-34207	
10.29†	Master Services Agreement, dated January 11, 2016, between the Company and inVentiv Commercial Services, LLC	10.30	10-K	March 8, 2018	001-34207	
10.30†	Project Agreement, dated October 31, 2017 between the Company and inVentiv Commercial Services, LLC	10.31	10-K	March 8, 2018	001-34207	
10.31†	First Amendment to Project Agreement, dated October 31, 2017 between Company and inVentiv Commercial Services, LLC	10.32	10-K	March 8, 2018	001-34207	
10.32†	Commercial Manufacturing and Supply Agreement, dated November 22, 2013, between Company and Baxter Pharmaceutical Solutions LLC	10.33	10-K	March 8, 2018	001-34207	
10.33†	Supply Agreement, dated November 2, 2016, between Company and Becton, Dickinson and Company	10.34	10-K	March 8, 2018	001-34207	
10.34†	Supply Agreement, dated October 1, 2012, between Company and Nitto Denko Avecia, Inc.	10.35	10-K	March 8, 2018	001-34207	
10.35†	Supply Agreement, dated July 27, 2016, between Company and West Pharmaceutical Services, Inc.	10.36	10-K	March 8, 2018	001-34207	
10.36	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, as amended.	10.1	10-Q	May 9, 2018	001-34207	
10.38	Sublicense Agreement, effective as of February 16, 2018, by and between the Company and Merck, Sharpe & Dohme Corp.	10.2	10-Q	May 9, 2018	001-34207	
10.39	Term Loan Agreement, dated as of February 20, 2018 among the Company, certain Lenders party hereto and CRG Servicing LLC, as agent for the Lenders	10.3	10-Q	May 9, 2018	001-34207	

Exhibit		Incorporated by Reference Exhibit				Filed
Number	Document	Number	Filing	Filing Date	File No.	Herewith
10.40†	2018 Equity Incentive Plan	10.1	8-K	June 1, 2018	001-34207	
10.41†	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan	10.2	8-K	June 1, 2018	001-34207	
10.42†	Form of Option Grant Notice and Option Agreement under the 2018 Equity Incentive Plan	10.3	8-K	June 1, 2018	001-34207	
10.43	Office/Laboratory Lease, dated September 17, 2018, between the Company and Emery Station West, LLC	10.1	10-Q	November 6, 2018	001-34207	
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Chief Executive Officer to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

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

† We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.
+ Indicates management contract, compensatory plan or arrangement.
* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-K), irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

Dynavax Technologies Corporation
By: /s/ EDDIE GRAY
Eddie Gray

Chief Executive Officer

(Principal Executive Officer)

Date: February 27, 2019

By: /s/ MICHAEL OSTRACH
Michael Ostrach

Chief Financial Officer

(Principal Financial Officer)

Date: February 27, 2019

By: /s/ DAVID JOHNSON
David Johnson

Vice President, Chief Accounting Officer

(Principal Accounting Officer)

Date: February 27, 2019

Signature	Title	Date
/s/ EDDIE GRAY Eddie Gray	Chief Executive Officer (Principal Executive Officer)	February 27, 2019
/s/ MICHAEL OSTRACH Michael Ostrach	Chief Financial Officer (Principal Financial Officer)	February 27, 2019
/s/ DAVID JOHNSON David Johnson	Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 27, 2019
/s/ ARNOLD L. ORONSKY, PH.D. Arnold L. Oronsky, Ph.D.	Chairman of the Board	February 27, 2019
/s/ LAURA BREGE Laura Brege	Director	February 27, 2019
/s/ FRANCIS R. CANO, PH.D. Francis R. Cano, Ph.D.	Director	February 27, 2019
/s/ DENNIS A. CARSON, M.D. Dennis A. Carson, M.D.	Director	February 27, 2019
Daniel L. Kisner, M.D.	Director	
/s/ PEGGY V. PHILLIPS Peggy V. Phillips	Director	February 27, 2019
/s/ NATALE S. RICCIARDI Natale S. Ricciardi	Director	February 27, 2019