# 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, 2019**

☐ **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.)* |

**2100 Powell Street, Suite 900**
**Emeryville, CA 94608**
**(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:** | **Trading symbol(s):** | **Name of each exchange on which registered:** |
|---|---|---|
| Common Stock, $0.001 par value | DVAX | 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 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 28, 2019 as reported on the Nasdaq Capital Market, was approximately $207,000,000. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 6, 2020, the registrant had outstanding 86,188,763 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Definitive Proxy Statement for the registrant's 2020 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, 2019.

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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®, our anticipated market opportunity and level of sales of HEPLISAV-B, our business, collaboration and regulatory strategy, our ability to manufacture commercial supply and meet regulatory requirements, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, liquidity and cash needs, as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout our document and can be identified by the use of forward-looking language such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," or "intend," or the negative of these terms or other variations or comparable terminology. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.*

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

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

## PART I

## ITEM 1. BUSINESS

### OVERVIEW

We are a fully-integrated biopharmaceutical company focused on developing and commercializing novel vaccines. 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 Phase 3 trials, HEPLISAV-B demonstrated faster and higher rates of protection with two doses in one month compared to another currently approved hepatitis B vaccine which requires three doses over six months, with a similar safety profile. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S.

### VACCINES AND VACCINE ADJUVANTS AND HEPLISAV-B'S NOVEL ADJUVANT 1018

Vaccines are products that stimulate a person's immune system to protect against a specific disease. Vaccines generally consist of a virus, bacteria or other pathogen, or a component, called an antigen, that can generate an immune response against that pathogen. Many antigens, including those used in recombinant subunit vaccines, are often poorly immunogenic and require additional components to help stimulate protective immunity based on antibodies and effector T cell functions. These additional components, called adjuvants, provide the help needed to enhance the immunogenicity of vaccine antigens. Adjuvants can increase the magnitude of an adaptive response to a vaccine and can guide the type of adaptive response to produce the most appropriate form of immunity for each specific pathogen.

HEPLISAV-B and each of the vaccines it directly competes against use recombinant hepatitis B surface antigen ("rHBsAg" or "HBsAg") to elicit an immune response to the virus. The other FDA approved HBV vaccines use aluminum as an adjuvant and we use 1018, our proprietary Toll-Like Receptor 9 ("TLR9') agonist adjuvant. In Phase 3 trials, HEPLISAV-B demonstrated faster and higher rates of protection and increased antibody titers and increased seroconversion rates in a general adult population and adult populations with reduced responsiveness with two doses in one month compared to three doses over six months required for a competitor product containing alum, and it had a similar safety profile.

#### Toll-like Receptor Immune Modulation Platform

Toll-like receptors ("TLRs") 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 work has been focused primarily on stimulation of a subset of TLRs that have evolved to recognize bacterial and viral nucleic acids. This work 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.

Our vaccine research to date has focused on the use of TLR9 agonists as novel vaccine adjuvants. CpG B-Class TLR9 agonists, such as our 1018 vaccine adjuvant, stimulate release of cytokines necessary for T cell activation and establishing long-term immunity. 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.

### OUR STRATEGY

Our primary objective is to make HEPLISAV-B the standard of care in the U.S. for immunization of adults against hepatitis B. Our strategy is to focus our commercial efforts on:

- converting the current market to HEPLISAV-B,
- development of a dosing regimen for the dialysis segment,
- expanding adult immunization and coverage rates,
- increasing second dose compliance, and
- expansion of the market to persons with diabetes.

In March 2019, we submitted, and the European Medicines Agency (“EMA”) accepted, our Marketing Authorization Application (“MAA”) for HEPLISAV-B. We are exploring territories where it would be commercially feasible to market on our own or through third parties.

We also are evaluating application of our adjuvant technology to additional vaccines, including our 1018 adjuvant. Our initial program is a collaboration with the Serum Institute of India Pvt. Ltd. to develop an improved pertussis vaccine.

**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. **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%).

We are conducting an open-label, single arm study evaluating HEPLISAV-B in adults with end stage renal disease who are initiating or undergoing hemodialysis. The study is designed to evaluate the immunogenicity and safety of a four-dose regimen in these subjects. Initial data are expected during 2020.

**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").

Total U.S. gross sales for adult hepatitis B vaccines are estimated to be approximately $400 million annually. The market opportunity could increase to over $700 million in gross sales annually with expanding adult immunization and coverage rates, increased second dose compliance, price increases and expansion of use in persons with diabetes. The largest segments of the market are concentrated in independent hospitals and clinics, integrated delivery networks, dialysis centers, public health clinics and prisons, the Departments of Defense and Veterans Affairs and retail pharmacies. Our promotional activity is focused on the largest accounts in each segment. We are currently targeting approximately 60% of hepatitis B vaccine sales in the U.S., with our field sales force of approximately 60 people across 6 regions. We are currently studying a four-dose regimen of HEPLISAV-B for patients on hemodialysis. Upon availability of this dosing schedule, we expect to add dialysis centers to our personal promotion efforts which could increase our coverage of the U.S. market to approximately 75%.

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. Additional sources of potential growth in the market opportunity include improved second dose compliance and increases in adult immunization and coverage rates.

**Post-Marketing Obligations Related to HEPLISAV-B**

Our FDA approval is subject to certain post-marketing obligations. For example, we are conducting an observational comparative study of HEPLISAV-B to Engerix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018 and is scheduled to continue through November 2020. In December 2019, we filed with the FDA a cumulative report on both interim analyses of the study. The event rates reflected in the interim analyses were similar between the two treatment arms. The independent data monitoring committee concurred the analyses showed no evidence of an increase in AMI events in the HEPLISAV-B arm as compared to the Engerix-B arm.

**INTELLECTUAL PROPERTY**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Generally, we seek patent protection in the U.S and 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, 2019, our intellectual property portfolio included over 25 issued U.S. patents, over 140 issued or granted foreign patents and over 40 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. Most of these patents and patent applications relate to our discontinued immuno-oncology programs. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that expire in 2032.

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 2021 to 2039.

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 in one month adult hepatitis B vaccine, competes directly with conventional three-dose over six months 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. A three dose HBV vaccine is reported to be under development by VBI Vaccines Inc ("VBI").

We are in competition with companies developing vaccines and vaccine adjuvants, including GSK, Pfizer, Inc., Sanofi S.A., Merck, Seqirus, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva SE and VBI.

Many of the entities developing or 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.

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 and local jurisdictions have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, register pharmaceutical sales representatives, 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, as defined by such law, and other healthcare professionals and teaching hospitals and ownership or investment interests held by such 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, 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 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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, solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization 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.

There remain 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, several 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". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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 December 2018, CMS published a new 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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 2029 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 HEPLISAV-B and 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, our headquarters is in a building certified as “Gold” level on the LEED Scorecard as set forth by the United States Green Building Committee. Additionally, the Company offers incentives to employees to utilize public transit in order to reduce traffic congestion and pollution and there is a free shuttle from our building to public transportation. 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, 2019, we had 231 employees, including 78 employees at our corporate headquarters in Emeryville, California, 54 field-based employees located throughout the U.S. and 99 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 2100 Powell Street, Suite 900, Emeryville, California, 94608. 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: 2100 Powell Street, Suite 900, Emeryville, California, 94608. 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, achieve restructuring goals, commercialize 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 healthcare products, because HEPLISAV-B is the company's first marketed product, the potential uptake of the product in distribution and the timing for growth in sales, if any, is 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 converted our contracted field sales team into full-time Dynavax employees in the second quarter of 2019. 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. Although 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, 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 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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 solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While a number of these and other measures may require additional authorization 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 implemented a strategic restructuring to prioritize our vaccine business and explore strategic alternatives for our immuno-oncology portfolio, and we cannot assure you that we will be able to successfully execute on a strategic alternative for our immuno-oncology portfolio.***

In the second quarter of 2019, we implemented a strategic restructuring that would focus our efforts on HEPLISAV-B, which included a reduction in our workforce and operations to focus resources on HEPLISAV-B commercialization and sales execution as well as assess additional opportunities to leverage our 1018 adjuvant. Additionally, we are seeking strategic alternatives for our immuno-oncology portfolio, including our development stage products such as SD-101 and DV281. In connection with the restructuring, we made the determination to wind down ongoing immuno-oncology trials. Our ability to successfully execute on a strategic alternative for our immuno-oncology portfolio is dependent on a number of factors and we may not be able to execute upon a transaction or other strategic alternative for our immuno-oncology portfolio upon favorable terms within an advantageous timeframe and recognize significant value for these assets, if at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative involving our immuno-oncology may be costly and time-consuming. Our strategic restructuring may not result in anticipated savings or other economic benefits, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

***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 in the United States is subject to certain post-marketing obligations and commitments to the FDA. For example, we must conduct an observational comparative study of HEPLISAV-B to Energix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018 and is scheduled to continue through November 2020. We must also t conduct an observational surveillance study to evaluate the incidence of new onset immune-mediated diseases, herpes zoster and anaphylaxis; and we are required to 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 or complete these studies to the satisfaction of FDA could result in withdrawal of our BLA approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. 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, any of which may have a material adverse effect on our business, results of operations, financial condition and prospects.

In December 2019, we filed with the FDA a cumulative report on both interim analyses of the ongoing observational comparative AMI study. The interim analyses were based on currently-available data, and the final results, related findings and conclusions of the study will not be known until its completion and the receipt and review of the complete study data. Interim results may not be reproduced in the future, and thus should be considered carefully and not relied upon as indicative of future study results. Material adverse differences in final data, compared to interim data, could significantly adversely affect our business and business prospects, including our future HEPLISAV-B business. Certain assumptions, estimations, calculations and conclusions may have been made in connection with the interim analyses of the study data, and others, including regulatory agencies, may not accept or agree with these assumptions, estimations, calculations or conclusions, or may interpret or weigh the importance of data differently, which could impact the actual or perceived value of the study, HEPLISAV-B or the Company in general.

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.

***If HEPLISAV-B or 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 HEPLISAV-B or any other products we develop, 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 as we have with HEPLISAV-B, 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 market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

***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. 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. A three dose HBV vaccine is reported to be under development by VBI Vaccines Inc ("VBI").

We are in competition with companies developing vaccines and vaccine adjuvants, including GSK, Pfizer, Sanofi, Merck, Seqirus, Agenus, Emergent BioSolutions, Novavax, Medicago and VBI.

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.

***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 years ended December 31, 2019 and 2018 were $152.6 million and $158.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of $1.2 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S., we expect to continue incurring 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 field sales force 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 historically increased our costs as we conducted more and larger studies to invest in clinical development. While we anticipate operating expenditures related to external oncology costs will decrease as a result of our strategic restructuring, 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.***

As of December 31, 2019, we had $151.1 million in cash, cash equivalents and marketable securities. We expect to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, manufacturing and seek strategic alternatives for our immuno-oncology product candidates. 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 significantly reduce our operations while we seek additional strategic alternatives, which could have an adverse impact on our ability to achieve our 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.

***We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates we may develop 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 HEPLISAV-B, or any other product candidates we may develop, 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.

In the event that we determine to pursue commercialization of HEPLISAV-B outside the United States, such as in Europe, 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 March, 2019, we submitted, and the European Medical Agency ("EMA") accepted, our Marketing Authorization Application ("MAA") for HEPLISAV-B. We may not be able to provide sufficient data or respond to comments to our MAA sufficient to obtain regulatory approval in Europe in a reasonable time period or at all.

The results of clinical trials conducted to support regulatory approval in one or more jurisdictions, and any failure or delay in obtaining regulatory approval in one or more jurisdictions, may have a negative effect on the regulatory approval process in other jurisdictions, including our regulatory approval in the United States. 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.

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

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA requirements are expensive and time consuming, may take more time to complete than expected or may not be completed, and may not have favorable outcomes. 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.

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.

***As a biopharmaceutical company, we engage CROs to conduct clinical studies, and 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 applicable 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 we or 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.

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.

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

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether a product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- a product candidate or combination study may appear to be no more effective than current therapies;
- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- the inability to obtain regulatory approval to conduct a clinical trial;

- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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

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

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

Our registration and commercial timelines depend on further discussions with 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.

***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, or reevaluate the viability of strategic alternatives.***

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 our clinical trials or our clinical trial strategy, or significantly reevaluate strategic alternatives. 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 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 supplier for 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce 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.

***HEPLISAV-B is subject to FDA obligations and continued regulatory review, and 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 for such products.***

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.

Further, in March, 2019, we submitted, and the EMA accepted, our MAA for HEPLISAV-B. We may not be able to provide sufficient data or respond to comments to our 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.

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.

***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 and research programs. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to continue to develop and commercialize those products and programs, if at all.***

We may need to establish collaborative relationships to obtain domestic and/or international sales, marketing, research, development and distribution capabilities for our product candidates and our discovery research programs. Failure to obtain a collaborative relationship for those product candidates and programs or HEPLISAV-B in markets outside the U.S. requiring extensive sales efforts, may significantly impair the potential for those products and programs and we may be required to raise additional capital to continue them. 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.

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. Despite our efforts, we may be unable to secure collaborative arrangements. 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.

***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 have borrowed $180.0 million, which includes paid-in-kind interest. 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 the period July 1, 2019 through June 30, 2020, the first period for which we are subject to such requirement. 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 focus on commercialization of HEPLISAV-B, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.***

As our commercial 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, “ACA”) 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, as defined by such law, and teaching hospitals, and ownership and investment interests held by such physicians 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 significant criminal, civil and administrative penalties, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), disgorgement, 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 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. There remain legal and political challenges to certain aspects of ACA, as well as 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, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of ACA. While Congress has not passed comprehensive repeal legislation, several 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 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”. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January l, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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 2029 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 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 other key scientific personnel. Our commercial and business efforts could be adversely affected by the loss of one or more key members of our commercial or management staff, including our senior executive officers. 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.

***Our business operations are vulnerable to interruptions by natural disasters, epidemics and other catastrophic events beyond our control, the occurrence of which could materially harm our manufacturing, distribution, sales, business operations and financial results.***

Our business operations are subject to interruption by natural disasters and other catastrophic events beyond our control, including, but not limited to, earthquakes, hurricanes, fires, droughts, tornadoes, electrical blackouts, public health crises and pandemics, war, terrorism, and geo-political unrest and uncertainties. We have not undertaken a systematic analysis of the potential consequences to our business that might result from any such natural disaster or other catastrophic event and have limited recovery plans in place. If any of these events occur, our manufacturing and supply chain, distribution, sales and marketing efforts and other business operations could be subject to business shutdowns or disruptions and financial results could be adversely affected. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions resulting from these events, but if we or any of the third parties with whom we engage, including the suppliers, contract manufacturers, distributors and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely affected in a number of ways, some of which are not predicable.

Our business could be adversely affected by health epidemics in regions where we have manufacturing facilities, sales activities or other business operations. For example, outbreaks of epidemic or pandemic diseases, such as might be caused by the COVID-19 coronavirus, or the fear of such events, could cause restrictions on supply chains, access to workplaces and affect employee health and availability. If the COVID-19 outbreak continues to spread, we may need to limit operations or implement limitations, including work from home policies. In addition, customers may postpone face to face meetings and impose restrictions on access by non-essential personnel in hospitals or clinics, all of which could slow adoption and implementation by some customers, resulting in lower sales.

Although we maintain inventories of HEPLISAV-B and its components, our ability and those of our contractors and distributors to produce and distribute HEPLISAV-B could be adversely affected. A pandemic or similar health challenge could severely impact the U.S. healthcare system, which may have an adverse effect on usage and sales of HEPLISAV-B. In addition, any such event could result in widespread global health crisis that could adversely affect global economies and

financial markets resulting in an economic downturn that could affect the demand for HEPLISAV-B and future revenue and operating results and our ability to raise additional capital when needed on acceptable terms, if at all.

Additionally, our corporate headquarters in Emeryville CA, is located in a seismically active region that also is subject to possible electrical shutdowns and wildfires. Because we do not carry earthquake insurance for earthquake-related losses and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake or catastrophic event. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us in excess of insured amounts could cause our business to materially suffer.

***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.

In the United States, California adopted the California Consumer Privacy Act of 2018 (“CCPA”), which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. It remains unclear how the CCPA will be interpreted, but as currently written, it will likely impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data. As we expand our operations, the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

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 that are intended 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.

***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 any 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.

Under our universal shelf registration statement, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our 2017 ATM 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, 2019, we have $118.6 million remaining under this agreement. The sale or issuance of our securities, including those issuable upon exercise of the outstanding warrants or conversion of the preferred stock, 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, 2019, we lease our facilities in Emeryville, California and Düsseldorf, Germany.

In July 2019, we entered into an agreement to sublease 23,976 square feet of office space located at 2100 Powell Street, Emeryville, California for our new global headquarters. This sublease agreement will continue until June 30, 2022. The lease for our former global headquarters at 2929 Seventh Street, Berkeley, California was terminated effective August 31, 2019.

In September 2018, we entered into an agreement to lease 75,662 square feet of laboratory and office space located at 5959 Horton Street, Emeryville, California ("Horton Street Lease"). Following our strategic organizational restructuring in May 2019, in July 2019, we entered into an agreement to sublease the entire 75,662 square feet to a third party ("Horton Street Sublease"). Both the Horton Street Lease and Horton Street Sublease will continue until March 31, 2031.

We also lease approximately 5,600 square meters of manufacturing 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, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations. We are not currently aware of any material legal proceedings involving the Company.

## 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 March 6, 2020, 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, 2019, 2018 and 2017 and the Consolidated Balance Sheets Data as of December 31, 2019 and 2018 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, 2016 and 2015 and the Consolidated Balance Sheets Data as of December 31, 2017, 2016 and 2015 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, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (In thousands, except per share data) | | | | |
| **Consolidated Statements of Operations Data:** | | | | | |
| Product revenue, net | $ 34,644 | $ 6,812 | $ - | $ - | $ - |
| Other revenue | 575 | 1,386 | 327 | 11,043 | 4,050 |
| Total revenues | 35,219 | 8,198 | 327 | 11,043 | 4,050 |
| Operating expenses: | | | | | |
| Cost of sales - product | 10,172 | 10,934 | - | - | - |
| Cost of sales - amortization of intangible assets | 9,217 | 10,862 | 1,194 | - | - |
| Research and development | 62,331 | 74,951 | 64,988 | 84,493 | 86,943 |
| Selling, general and administrative | 74,986 | 64,770 | 27,367 | 37,257 | 22,180 |
| Restructuring | 13,356 | - | 2,783 | - | - |
| Total operating expenses | 170,062 | 161,517 | 96,332 | 121,750 | 109,123 |
| Loss from operations | (134,843) | (153,319) | (96,005) | (110,707) | (105,073) |
| Other income (expense): | | | | | |
| Interest income | 3,370 | 3,828 | 1,337 | 755 | 205 |
| Interest expense | (16,977) | (9,338) | - | - | (572) |
| Sublease income | 2,619 | - | - | - | - |
| Change in fair value of warrant liability | (7,500) | - | - | - | - |
| Other income (expense), net | 731 | (70) | (486) | (2,492) | 317 |
| Loss on extinguishment of debt | - | - | - | - | (1,671) |
| Net loss | (152,600) | (158,899) | (95,154) | (112,444) | (106,794) |
| Preferred stock deemed dividend(1) | (3,267) | - | - | - | - |
| Net loss allocable to common stockholders | $ (155,867) | $ (158,899) | $ (95,154) | $ (112,444) | $ (106,794) |
| Net loss per share allocable to common stockholders - basic and diluted | $ (2.16) | $ (2.55) | $ (1.81) | $ (2.92) | $ (3.25) |
| Weighted average shares used to compute basic and diluted net loss per share allocable to common stockholders | 72,024 | 62,362 | 52,613 | 38,506 | 32,881 |

(1) Deemed dividend related to beneficial conversion feature of convertible preferred stock. The fair value of the common stock into which the Series B Preferred Stock was convertible exceeded the allocated purchase price of the Series B Preferred Stock by $3.3 million on the date of issuance, resulting in a deemed dividend. The Company recognized the deemed dividend as a one-time, non-cash, deemed dividend to the holders of Series B Preferred Stock on the date of issuance, which is the date the stock first became convertible.

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (In thousands) | | | | |
| **Consolidated Balance Sheets Data:** | | | | | |
| Cash, cash equivalents and marketable securities | $ 151,055 | $ 145,536 | $ 191,854 | $ 81,415 | $ 196,125 |
| Working capital | 155,606 | 136,331 | 179,430 | 69,563 | 171,161 |
| Total assets(2) | 279,068 | 210,884 | 218,785 | 109,680 | 216,633 |
| Long-term debt, net | 178,601 | 100,871 | - | - | - |
| Accumulated deficit | (1,218,824) | (1,066,224) | (907,325) | (812,171) | (699,727) |
| Total stockholders' equity | 8,290 | 63,065 | 199,549 | 89,201 | 187,079 |

(2) The December 31, 2019 balance includes operating lease right-of-use assets of $30.3 million as a result of the ASC 842 adoption on January 1, 2019.

## 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 developing and commercializing novel vaccines. 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 Phase 3 trials, HEPLISAV-B demonstrated faster and higher rates of protection with two doses in one month compared to another currently approved hepatitis B vaccine which requires three doses over six months, with a similar safety profile. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S.

We have 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 and Recombivax-HB® from Merck & Co.

All of product revenue is from sales of HEPLISAV-B to certain wholesalers and specialty distributors in the U.S. whose principal customers include independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Departments of Defense and Veterans Affairs and retail pharmacies. For the year ended December 31, 2019, product revenue, net was $34.6 million.

On May 23, 2019, we implemented a strategic organizational restructuring, principally to align our operations around our vaccine business and significantly curtail further investment in our immuno-oncology business. In connection with the restructuring, we reduced our workforce by approximately 80 positions, or approximately 36%, of U.S.-based personnel. We have completed our restructuring activities and recognized restructuring costs of $13.4 million in 2019.

In February 2018, we entered into a term loan agreement with CRG Servicing LLC. We borrowed $100 million at closing and the remaining $75.0 million in March 2019. At December 31, 2019, the balance of the term loan was $178.6 million and the loan and related unpaid interest and fees are due in December 2023.

In August 2019, we sold 18,525,000 shares of common stock, 4,840 shares of Series B Convertible Preferred Stock and warrants to purchase an aggregate of 5,841,250 shares of common stock in an underwritten public offering. Total net proceeds from the offering were approximately $65.6 million. In addition, for the year ended December 31, 2019, we received net cash proceeds of $13.9 million from sales of 1,386,906 shares of our common stock under the At Market Sales Agreement with Cowen and Company, LLC entered in November 2017.

### 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, inventories and leases. 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***

We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Accounting Standards Codification ("ASC") 606, we perform 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) we satisfy 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, pharmacies 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 years ended December 31, 2019 and 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, pharmacies and others. In addition to distribution agreements with Customers, we enter into arrangements with qualified 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 providers 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 the qualified healthcare providers, and chargebacks for units that our Customers have sold to the qualified 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.

*Rebates:* Under certain contracts, customers may obtain rebates for purchasing minimum volumes of our product. We estimate these rebates based upon the expected purchases and the contractual rebate rate and record this estimate as a reduction in revenue in the period the related revenue is recognized.

*Collaboration and Manufacturing Service Revenue*

We have entered into collaborative arrangements and arrangements to provide manufacturing services to 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. Manufacturing service revenue is included in other revenue in our consolidated statements of operations.

***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 during the years presented.

***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.

***Inventories***

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. 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.

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 the vial presentation of 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 resuming manufacturing 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.

***Leases***

On January 1, 2019, we adopted ASC 842, Leases, using the modified retrospective approach. Prior period amounts continue to be reported in accordance with our historic accounting under previous lease guidance, ASC 840, Leases. We elected the package of practical expedients which, among other things, allowed us to carry forward the historical lease classification of leases in place as of January 1, 2019. We have also elected the practical expedient to not separate lease components from non-lease components. As a result of adopting ASC 842, we recognized right-of-use asset and lease liabilities for operating leases of $34.8 million and $37.1 million, respectively on January 1, 2019. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption of ASC 842.

We determine if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities and long-term portion of lease liabilities in our consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, we use our incremental borrowing rate which represents an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date.

Our leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. We have elected not to apply the recognition requirements of ASC 842 for short-term leases.

As lessors, we determine if an arrangement includes a lease at inception. We elected the practical expedient to not separate lease components from non-lease components. Sublease income is recognized on a straight-line basis over the expected lease term and is included in other income (expense) in our consolidated statements of operations.

***Restructuring***

Restructurings costs are comprised of severance, other termination benefit costs, stock-based compensation expense for stock award and stock option modifications related to workforce reductions and accelerated depreciation. We recognize restructuring charges when the liability is probable and the amount is estimable. Employee termination benefits are accrued at the date management has committed to a plan of termination and affected employees have been notified of their termination date and expected severance benefits.

***Recent Accounting Pronouncements***

***Accounting Standards Update 2016-13***

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. As a smaller reporting company, this ASU and its subsequent updates, is effective for fiscal years beginning after December 15, 2022. We are currently evaluating the impact this standard will have on our consolidated financial statements.

**Results of Operations**

***Revenues***

Revenues consisted of amounts earned from product sales, manufacturing service and collaboration revenue.

Product revenue, net, reflects sales of HEPLISAV-B. We commenced commercial shipments of HEPLISAV-B in January 2018, deployed our field sales force in February 2018 and, in April 2019, converted the external sales force to our employees.

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.

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

| | Year Ended December 31, | | | Increase (Decrease) from 2018 to 2019 | | Increase (Decrease) from 2017 to 2018 | |
|---|---|---|---|---|---|---|---|
| **Revenues:** | **2019** | **2018** | **2017** | **$** | **%** | **$** | **%** |
| Product revenue, net | $ 34,644 | $ 6,812 | $ - | $ 27,832 | 409% | $ 6,812 | NM |
| Collaboration revenue | 143 | 1,386 | - | (1,243) | (90)% | 1,386 | NM |
| Other revenue | 432 | - | 327 | 432 | NM | (327) | NM |
| Total revenues | $ 35,219 | $ 8,198 | $ 327 | $ 27,021 | 330% | $ 7,871 | NM |

*NM = Not meaningful*

*2019 versus 2018*

For the year ended December 31, 2019, product revenue, net increased due to higher volume as additional healthcare providers completed operational activities required to switch to HEPLISAV-B and existing customers placed repeat orders. We expect quarterly sales will increase during 2020 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. At our current scale, quarterly product sales can be affected by variations in seasonal factors such as the lower Department of Defense purchases following the summer surge of new recruits, days lost to holiday periods, which can delay implementation and ordering by customers, and the stocking patterns of our distributors.

Collaboration revenue relates to services performed in 2019 under a collaboration agreement with Serum Institute of India Pvt. Ltd. Other revenue includes manufacturing service revenue of $0.4 million.

*2018 versus 2017*

Initial sales 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.

Collaboration revenue relates to services performed in 2018 under a collaboration agreement with Serum Institute of India Pvt. Ltd.

***Cost of Sales – Product***

The following is a summary of our cost of sales - product (in thousands, except for percentages):

| | Year Ended December 31, | | | Increase (Decrease) from 2018 to 2019 | | Increase (Decrease) from 2017 to 2018 | |
|---|---|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | $ | % | $ | % |
| Cost of sales - product | $ 10,172 | $ 10,934 | $ - | $ (762) | (7)% | $ 10,934 | NM |

*2019 versus 2018*

Cost of sales - product for the year ended December 31, 2019 primarily includes certain fill, finish and overhead costs for pre-filled syringes (“PFS”) of HEPLISAV-B and costs related to a terminated batch. Our HEPLISAV-B PFS finished goods inventory includes components for which a portion of the manufacturing costs were previously expensed to research and development prior to the approval of the PFS presentation by the FDA in March 2018. We expect to use this HEPLISAV-B PFS inventory over approximately the next six to nine months. We expect cost of sales of HEPLISAV-B PFS, on a per unit basis, to increase as we produce and then sell inventory that reflects the full cost of manufacturing the product.

At December 31, 2019, inventories, net increased to $41.3 million from $19.0 million at December 31, 2018 to support increased projected sales.

***Cost of Sales - Amortization of Intangible Assets***

The following is a summary of our cost of sales – amortization of intangible assets (in thousands, except for percentages):

| | Year Ended December 31, | | | Increase (Decrease) from 2018 to 2019 | | Increase (Decrease) from 2017 to 2018 | |
|---|---|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | $ | % | $ | % |
| Cost of sales - amortization of intangible assets | $ 9,217 | $ 10,862 | $ 1,194 | $ (1,645) | (15)% | $ 9,668 | 810% |

Cost of sales - amortization of intangible assets 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. The intangible assets related to Coley and GSK have been fully-amortized in 2018. At December 31, 2019, the intangible asset related to Merck of $2.5 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, process 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.

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

| Research and Development: | Year Ended December 31, 2019 | 2018 | 2017 | Increase (Decrease) from 2018 to 2019 $ | % | Increase (Decrease) from 2017 to 2018 $ | % |
|---|---|---|---|---|---|---|---|
| Compensation and related personnel costs | $ 21,933 | $ 30,466 | $ 28,577 | $ (8,533) | (28)% | $ 1,889 | 7% |
| Outside services | 25,437 | 28,213 | 20,112 | $ (2,776) | (10)% | 8,101 | 40% |
| Facility costs | 6,903 | 6,668 | 8,472 | $ 235 | 4% | (1,804) | (21)% |
| Non-cash stock-based compensation | 8,058 | 9,604 | 7,827 | $ (1,546) | (16)% | 1,777 | 23% |
| Total research and development | $ 62,331 | $ 74,951 | $ 64,988 | $ (12,620) | (17)% | $ 9,963 | 15% |

In May 2019 we announced a strategic organizational restructuring to align our operations around our vaccine business and significantly curtail further investment in immuno-oncology research and development.

*2019 versus 2018*

Compensation and related personnel costs and non-cash stock-based compensation decreased in the 2019 periods compared to the 2018 periods due to lower research and development headcount as a result of our restructuring in May 2019. Outside services in 2019 decreased versus the comparable period in 2018 due to an overall reduction in costs to support the development of SD-101 and earlier stage immuno-oncology programs after the restructuring.

*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 period, facility costs, which include an overhead allocation of occupancy and related expenses, included full operating costs of our Düsseldorf facility.

***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 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):

| Selling, General and Administrative: | Year Ended December 31, 2019 | 2018 | 2017 | Increase (Decrease) from 2018 to 2019 $ | % | Increase (Decrease) from 2017 to 2018 $ | % |
|---|---|---|---|---|---|---|---|
| Compensation and related personnel costs | $ 28,525 | $ 15,993 | $ 8,685 | $ 12,532 | 78% | $ 7,308 | 84% |
| Outside services | 26,269 | 31,758 | 7,611 | (5,489) | (17)% | 24,147 | 317% |
| Legal costs | 2,293 | 2,792 | 2,777 | (499) | (18)% | 15 | 1% |
| Facility costs | 7,675 | 2,466 | 1,204 | 5,209 | 211% | 1,262 | 105% |
| Non-cash stock-based compensation | 10,224 | 11,761 | 7,090 | (1,537) | (13)% | 4,671 | 66% |
| Total selling, general and administrative | $ 74,986 | $ 64,770 | $ 27,367 | $ 10,216 | 16% | $ 37,403 | 137% |

*2019 versus 2018*

The increase in compensation and related personnel costs and the related decrease in outside services was due to the conversion of the external sales force to our employees effective April 1, 2019. The corresponding decrease in outside services was partially offset by an increase in post-marketing study costs for completion of certain milestones in the HEPLISAV-B post marketing study, and costs for increased sales and marketing activities. Legal costs decreased primarily due to outside counsel costs incurred in the first quarter of 2018 in connection with the loan financing. Facility costs, which include an overhead allocation of occupancy and related expenses, increased primarily due to additional rent costs pursuant to our 5959 Horton Street lease. We are recouping these additional rent costs through our sublease of the space to a third party. The related sublease income is being recorded as part of other income (expense) in our consolidated statement of operations. Non-cash stock-based compensation decreased compared to the prior period due to the timing of vesting of certain stock awards granted in 2017.

*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. 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.

***Restructuring***

On May 23, 2019, we implemented a strategic organizational restructuring, principally to align our operations around our vaccine business and significantly curtail further investment in our immuno-oncology business. In connection with the restructuring, we reduced our workforce by approximately 80 positions, or by approximately 36%, of U.S.-based personnel. We have completed our restructuring activities and recognized restructuring costs of $13.4 million in 2019.

***Other Income (Expense)***

Interest income is reported net of amortization of premiums and discounts on marketable securities. Interest expense 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. Sublease income is recognized in connection with our sublease of office and laboratory space. Change in fair value of warrant liability reflects the changes in fair value of warrants issued in connection with equity financing in August 2019. Other income, net includes gains and losses on foreign currency transactions and disposal of property and equipment.

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

| | Year Ended December 31, | | | Increase (Decrease) from 2018 to 2019 | | Increase (Decrease) from 2017 to 2018 | |
|---|---|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | $ | % | $ | % |
| Interest income | $ 3,370 | $ 3,828 | $ 1,337 | $ (458) | (12)% | $ 2,491 | 186% |
| Interest expense | $ (16,977) | $ (9,338) | $ - | $ 7,639 | 82% | $ 9,338 | NM |
| Sublease income | $ 2,619 | $ - | $ - | $ 2,619 | NM | $ - | NM |
| Change in fair value of warrant liability | $ (7,500) | $ - | $ - | $ 7,500 | NM | $ - | NM |
| Other income (expense), net | $ 731 | $ (70) | $ (486) | $ 801 | 1,144% | $ (416) | (86)% |

*NM = Not meaningful*

*2019 versus 2018*

Interest expense increased due to the borrowing of the remaining $75.0 million in March 2019 under the term loan agreement with CRG Servicing LLC (“Loan Agreement”). During 2019, we recognized sublease income of $2.6 million in connection with our sublease of office and laboratory space located at 5959 Horton Street, Emeryville, California to a third party. The change in the fair value of the warrant liability is primarily due to increase in our stock price. The change in other income, net is primarily due to foreign currency transactions and related fluctuations in the value of the Euro compared to the U.S. dollar.

*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 and related fluctuations in the value of the Euro compared to the U.S. dollar.

**Liquidity and Capital Resources**

As of December 31, 2019, we had $151.1 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, borrowings, government grants and revenues from product sales and 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 as of December 31, 2019, and anticipated revenues from HEPLISAV-B will be sufficient to fund our operations for at least the next 12 months from the date of this filing.

At December 31, 2019, $118.6 million of common stock remained available for sale under our At Market Sales Agreement with Cowen and Company, LLC (“2017 ATM Agreement”). Subsequent to December 31, 2019 and through March 11, 2020, we sold 2,180,266 shares of common stock for net proceeds of $11.7 million under the 2017 ATM Agreement.

We expect to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B. If we cannot 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 significantly reduce our operations 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.

*2019 versus 2018*

During the year ended December 31, 2019, we used $121.3 million of cash for our operations primarily due to our net loss of $152.6 million, of which $58.0 million consisted of non-cash charges such as stock-based compensation, amortization of intangible assets, depreciation and amortization, change in fair value of warrant liability, non-cash interest expense, amortization of right-of-use assets and accretion and amortization on marketable securities. 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, amortization of intangible assets, depreciation and amortization, non-cash interest expense and accretion and amortization on marketable securities. Cash used in our operations during 2019 decreased by $10.0 million. For the year ended December 31, 2019, we received tenant improvement reimbursements from the landlord of 5959 Horton Street totaling $7.0 million. During the year ended December 31, 2019, we invested approximately $22.3 million in HEPLISAV-B inventory to support increased projected sales. 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, 2019, cash used in investing activities was $42.8 million compared to $55.5 million of cash provided by investing activities for the year ended December 31, 2018. Cash used in investing activities during the year ended December 31, 2019 included $13.4 million of net purchases of marketable securities compared to $70.7 million of net proceeds from maturities of marketable securities during 2018. During the year ended December 31, 2019, we paid $7.0 million of sublicense payment Merck compared to $11.0 million of milestone and sublicense payments to Coley, Merck and GSK during 2018. Net cash used in the purchases of property plant and equipment increased by $18.2 million from 2018 to 2019. The increase is, primarily, due to the installation of facility improvements.

During the year ended December 31, 2019 and 2018, net cash provided by financing activities was $154.4 million and $99.1 million, respectively. Cash provided by financing activities for the year ended December 31, 2019 included net proceeds of $74.3 million from the second tranche of the Loan Agreement, net proceeds of $52.0 million and $13.6 million from the issuance of common stock and Series B Convertible Preferred Stock, respectively, from our underwritten public offering in August 2019 and net proceeds of $13.9 million from the issuance of common stock under our 2017 ATM Agreement. During the year ended December 31, 2018, we received net cash proceeds of $99.0 million from the Loan Agreement.

*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, amortization of intangible assets, depreciation and amortization, non-cash interest expense 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 5959 Horton Street, Emeryville, California 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.

***Contractual Obligations***

The following summarizes our significant contractual obligations at December 31, 2019 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

| Contractual Obligations: | Total | 2020 | 2021-2022 | 2023-2024 | 2025 and Thereafter |
|---|---|---|---|---|---|
| Operating leases | $ 64,649 | $ 7,023 | $ 13,153 | $ 9,913 | $ 34,560 |
| Long-term debt obligation | 187,195 | - | - | 187,195 | - |
| Purchase commitments | 7,561 | 7,561 | - | - | - |
| Sublicense agreement | 7,000 | 7,000 | - | | - |
| Total contractual obligations | $ 266,405 | $ 21,584 | $ 13,153 | $ 197,108 | $ 34,560 |

We lease our facilities in Emeryville, California and Düsseldorf, Germany.

In July 2019, we entered into an agreement to sublease 23,976 square feet of office space located at 2100 Powell Street, Emeryville, California for our new global headquarters. This sublease agreement will continue until June 30, 2022. As of December 31, 2019, we are obligated to make lease payments totaling $2.9 million, plus any operating expenses and taxes over the lease term.

In September 2018, we entered into an agreement to lease 75,662 square feet of laboratory and office space located at 5959 Horton Street, Emeryville, California at the rate of $4.75 per square foot, paid on a monthly basis (“Horton Street Lease”). As of December 31, 2019, we are obligated to make lease payments totaling $58.0 million, plus any operating expenses and taxes over the Horton Street Lease term. In July 2019, we entered into an agreement to sublease the entire 75,662 square feet to a third party at the rate of $5.50 per square foot, paid on a monthly basis (“Horton Street Sublease”). Both the Horton Street Lease and the Horton Street Sublease will continue until March 31, 2031.

We also lease our facility in Düsseldorf, Germany (“Düsseldorf Lease”) under an operating lease that expires in March 2023 with an option to renew for two five-year term. As of December 31, 2019, we are obligated to make lease payments totaling $1.7 million, plus any operating expenses and taxes over the lease term. 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, 2019 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, 2019 and 2018.

On February 20, 2018, we entered into a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. We borrowed $100.0 million under the Loan Agreement at closing and the remaining $75.0 million in March 2019 (collectively, “Term Loans”). 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, 2019, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $178.6 million, net of debt discount of $1.4 million. Included in our total contractual obligations of $187.2 million is the principal amount of $175.0 million, paid-in-kind interest of $5.0 million and the backend facility fee of $7.2 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid.

In February 2018, we entered into a sublicense agreement with Merck, Sharpe & Dohme Corp. Under the agreement, we paid the third and last installment of $7.0 million in February 2020.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B. 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, 2019.

***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 investments would be $1.1 million or $1.3 million, respectively.

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

***Foreign Currency Risk***

We have certain investments outside the U.S. for the operations of Dynavax GmbH with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2019 was $2.5 million primarily related to translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2019, 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 11, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments effective January 1, 2019.

**Basis for Opinion**

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

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

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2002
San Francisco, California
March 11, 2020

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

**(In thousands, except per share amounts)**

| | December 31, | |
|---|---|---|
| | **2019** | **2018** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 39,884 | $ 49,348 |
| Marketable securities available-for-sale | 111,171 | 96,188 |
| Accounts and other receivables, net | 8,886 | 3,704 |
| Inventories, net | 41,332 | 19,022 |
| Prepaid expenses and other current assets | 7,380 | 6,102 |
| Total current assets | 208,653 | 174,364 |
| Property and equipment, net | 32,022 | 17,064 |
| Intangible assets, net | 2,500 | 11,717 |
| Operating lease right-of-use assets | 30,252 | - |
| Goodwill | 2,081 | 2,144 |
| Restricted cash | 216 | 619 |
| Other assets | 3,344 | 4,976 |
| Total assets | $ 279,068 | $ 210,884 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,278 | $ 5,278 |
| Accrued research and development | 4,120 | 9,714 |
| Accrued liabilities | 14,802 | 16,041 |
| Warrant liability | 14,860 | - |
| Other current liabilities | 9,987 | 7,000 |
| Total current liabilities | 53,047 | 38,033 |
| Long-term debt, net | 178,601 | 100,871 |
| Long-term portion of lease liabilities | 37,845 | - |
| Other long-term liabilities | 1,285 | 8,915 |
| Total liabilities | 270,778 | 147,819 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock: $0.001 par value | - | - |
| Authorized: 5,000 shares; Issued and outstanding: | | |
| Series B Convertible Preferred Stock — 5 shares at December 31, 2019 and no shares at December 31, 2018 | | |
| Common stock: $0.001 par value; 139,000 shares authorized at December 31, 2019 and 2018; 83,871 and 62,862 shares issued and outstanding at December 31, 2019 and 2018, respectively | 84 | 63 |
| Additional paid-in capital | 1,229,417 | 1,131,241 |
| Accumulated other comprehensive loss | (2,387) | (2,015) |
| Accumulated deficit | (1,218,824) | (1,066,224) |
| Total stockholders' equity | 8,290 | 63,065 |
| Total liabilities and stockholders' equity | $ 279,068 | $ 210,884 |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**(In thousands, except per share amounts)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Revenues: | | | |
| Product revenue, net | $ 34,644 | $ 6,812 | $ - |
| Collaboration revenue | 143 | 1,386 | - |
| Other revenue | 432 | - | 327 |
| Total revenues | 35,219 | 8,198 | 327 |
| Operating expenses: | | | |
| Cost of sales - product | 10,172 | 10,934 | - |
| Cost of sales - amortization of intangible assets | 9,217 | 10,862 | 1,194 |
| Research and development | 62,331 | 74,951 | 64,988 |
| Selling, general and administrative | 74,986 | 64,770 | 27,367 |
| Restructuring | 13,356 | - | 2,783 |
| Total operating expenses | 170,062 | 161,517 | 96,332 |
| Loss from operations | (134,843) | (153,319) | (96,005) |
| Other income (expense): | | | |
| Interest income | 3,370 | 3,828 | 1,337 |
| Interest expense | (16,977) | (9,338) | - |
| Sublease income | 2,619 | - | - |
| Change in fair value of warrant liability | (7,500) | - | - |
| Other income (expense), net | 731 | (70) | (486) |
| Net loss | (152,600) | (158,899) | (95,154) |
| Preferred stock deemed dividend | (3,267) | - | - |
| Net loss allocable to common stockholders | $ (155,867) | $ (158,899) | $ (95,154) |
| Net loss per share allocable to common stockholders - basic and diluted | $ (2.16) | $ (2.55) | $ (1.81) |
| Weighted average shares used to compute basic and diluted net loss per share allocable to common stockholders | 72,024 | 62,362 | 52,613 |

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(In thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Net loss | $ (152,600) | $ (158,899) | $ (95,154) |
| Other comprehensive (loss) income, net of tax: | | | |
| Unrealized gain (loss) on marketable securities available-for-sale | 140 | 12 | (83) |
| Cumulative foreign currency translation adjustments | (512) | (1,146) | 2,826 |
| Total other comprehensive (loss) income | (372) | (1,134) | 2,743 |
| Total comprehensive loss | $ (152,972) | $ (160,033) | $ (92,411) |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

**(In thousands)**

| | Common Stock | | Preferred Stock | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Par Amount | Shares | Par Amount | Additional Paid-In Capital | Accumulated Other Comprehensive (Loss) Income | Accumulated Deficit | Total Stockholders' Equity |
| 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 |
| Issuance of common stock upon exercise of stock options and restricted stock awards, net | 975 | 1 | - | - | 1 | - | - | 2 |
| Issuance of common stock under Employee Stock Purchase Plan | 122 | - | - | - | 565 | - | - | 565 |
| Issuance of common stock, net of issuance costs, in conjunction with an underwritten public offering and an At Market Sales Agreement (see Note 14) | 19,912 | 20 | - | - | 60,093 | - | - | 60,113 |
| Issuance of Series B Convertible Preferred Stock, net of issuance costs, in conjunction with an underwritten public offering (see Note 14) | - | - | 5 | - | 12,061 | - | - | 12,061 |
| Stock compensation expense | - | - | - | - | 25,456 | - | - | 25,456 |
| Total other comprehensive loss | - | - | - | - | - | (372) | - | (372) |
| Net loss | - | - | - | - | - | - | (152,600) | (152,600) |
| Balances at December 31, 2019 | 83,871 | $ 84 | 5 | $ - | $ 1,229,417 | $ (2,387) | $ (1,218,824) | $ 8,290 |

*See accompanying notes.*

**DYNAVAX TECHNOLOGIES CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(In thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 (As Adjusted) |
| **Operating activities** | | | |
| Net loss | $ (152,600) | $ (158,899) | $ (95,154) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 8,938 | 3,621 | 3,244 |
| Amortization of right-of-use assets | 3,375 | - | - |
| Loss (gain) on disposal of property and equipment | 18 | 98 | (10) |
| Accretion of discounts and amortization of premiums on marketable securities | (1,462) | (1,559) | (193) |
| Change in fair value of warrant liability | 7,500 | - | - |
| Reversal of deferred rent upon lease amendment | | - | (209) |
| Stock compensation expense | 25,456 | 23,478 | 14,917 |
| Cost of sales - amortization of intangible assets | 9,217 | 10,862 | 1,194 |
| Non-cash interest expense | 4,973 | 2,755 | - |
| Tenant improvements provided by the landlord | 6,999 | - | - |
| Changes in operating assets and liabilities: | | | |
| Accounts and other receivables, net | (5,182) | (2,850) | 488 |
| Inventories, net | (22,310) | (18,710) | (312) |
| Prepaid expenses and other current assets | (1,278) | (2,405) | (1,830) |
| Other assets | 1,632 | (3,706) | (936) |
| Accounts payable | 4,848 | 3,417 | (1,915) |
| Lease liabilities | (2,000) | - | - |
| Accrued liabilities and other long-term liabilities | (9,376) | 12,597 | 3,198 |
| Net cash used in operating activities | (121,252) | (131,301) | (77,518) |
| **Investing activities** | | | |
| Acquisition of technology licenses | (7,000) | (11,000) | - |
| Purchases of marketable securities | (215,191) | (213,804) | (227,672) |
| Proceeds from maturities and redemptions of marketable securities | 201,810 | 284,457 | 119,638 |
| Purchases of property and equipment, net | (22,401) | (4,187) | (669) |
| Net cash (used in) provided by investing activities | (42,782) | 55,466 | (108,703) |
| **Financing activities** | | | |
| Proceeds from long-term debt, net | 74,250 | 99,000 | - |
| Proceeds from issuances of common stock, net | 65,948 | - | 185,936 |
| Proceeds from issuances of preferred stock, net | 13,586 | - | - |
| Proceeds (tax withholding) from exercise of stock options and restricted stock awards, net | 2 | (523) | 1,613 |
| Proceeds from Employee Stock Purchase Plan | 565 | 594 | 293 |
| Net cash provided by financing activities | 154,351 | 99,071 | 187,842 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (184) | (482) | 701 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (9,867) | 22,754 | 2,322 |
| Cash, cash equivalents and restricted cash at beginning of year | 49,967 | 27,213 | 24,891 |
| Cash, cash equivalents and restricted cash at end of year | $ 40,100 | $ 49,967 | $ 27,213 |
| **Supplemental disclosure of cash flow information** | | | |
| Cash paid during the year for interest | $ 12,147 | $ 6,583 | $ - |
| Release of accrual for litigation settlement and insurance recovery | $ - | $ - | $ 4,975 |
| Non-cash investing and financing activities: | | | |
| Non-cash acquisition of technology license | $ - | $ 12,773 | $ - |
| Purchases of property and equipment, not yet paid | $ 2,698 | $ 920 | $ 378 |
| Proceeds allocated to warrant liability at issuance | $ 7,360 | $ - | $ - |
| Right-of-use assets obtained in exchange for operating lease liabilities | $ 40,626 | $ - | $ - |

*See accompanying notes.*

## 1. Organization

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. We launched our first product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following United States Food and Drug Administration ("FDA") approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. 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: discovery, development and commercialization of novel vaccines.

### Liquidity and Financial Condition

As of December 31, 2019, we had cash, cash equivalents and marketable securities of $151.1 million.

The Company has incurred losses and negative cash flows from operations since its inception and expects to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B. If we cannot 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.

We currently anticipate that our cash, cash equivalents and short-term marketable securities as of December 31, 2019, and anticipated revenues from HEPLISAV-B will be sufficient to fund our operations for at least the next 12 months from the date of this filing.

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.

### 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, 2019, 2018 and 2017, we reported an unrealized (loss) gain of $(0.5) million, $(1.1) million and $2.8 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, 2019, 2018 and 2017, we reported a gain (loss) of $0.2 million, $0.3 million and $(0.6) 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. 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, 2019, 2018 and 2017, 100%, 83% and 90%, respectively, of our revenues were earned in the United States. As of December 31, 2019 and 2018, 62% and 24%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

Our source of product revenue consists of sales of HEPLISAV-B. We have entered into distribution agreements with a limited number of wholesalers and specialty distributors in the U.S. All of our product revenue is from these customers. For the year ended December 31, 2019 and 2018, our three largest customers collectively represented approximately 62% and 68% of our product revenue, respectively. As of December 31, 2019 and 2018, our three largest customers collectively represented approximately 76% 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. We primarily use actual costs to determine our cost basis for inventories. 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.

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 the vial presentation of 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 resuming manufacturing 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 has 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. In the third quarter of 2019, we recorded accelerated depreciation of $3.0 million related to certain long-lived assets. See Note 17.

**Leases**

On January 1, 2019, we adopted ASC 842, Leases, using the modified retrospective approach. Prior period amounts continue to be reported in accordance with our historic accounting under previous lease guidance, ASC 840, Leases. We elected the package of practical expedients which, among other things, allowed us to carry forward the historical lease classification of leases in place as of January 1, 2019. We have also elected the practical expedient to not separate lease components from non-lease components. As a result of adopting ASC 842, we recognized right-of-use asset and lease liabilities for operating leases of $34.8 million and $37.1 million, respectively on January 1, 2019. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption of ASC 842.

We determine if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities and long-term portion of lease liabilities in our consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, we use our incremental borrowing rate which represents an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date.

Our leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. We have elected not to apply the recognition requirements of ASC 842 for short-term leases.

As lessors, we determine if an arrangement includes a lease at inception. We elected the practical expedient to not separate lease components from non-lease components. Sublease income is recognized on a straight-line basis over the expected lease term and is included in other income (expense) in our consolidated statements of operations.

**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 impairment has been identified for the years presented.

**Revenue Recognition**

We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Accounting Standards Codification ("ASC") 606, we perform 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) we satisfy 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, pharmacies 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 years ended December 31, 2019 and 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, pharmacies and others. In addition to distribution agreements with Customers, we enter into arrangements with qualified 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 providers 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 the qualified healthcare providers, and chargebacks for units that our Customers have sold to the qualified 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.

*Rebates:* Under certain contracts, customers may obtain rebates for purchasing minimum volumes of our product. We estimate these rebates based upon the expected purchases and the contractual rebate rate and record this estimate as a reduction in revenue in the period the related revenue is recognized.

*Collaboration and Manufacturing Service Revenue*

We have entered into collaborative arrangements and arrangements to provide manufacturing services to 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. Manufacturing service revenue is included in other revenue in our consolidated statements of operations.

**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 during the years presented.

**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, 2019 and 2018. 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.

**Restructuring**

Restructuring costs are comprised of severance, other termination benefit costs, stock-based compensation expense for stock award and stock option modifications related to workforce reductions and accelerated depreciation. We recognize restructuring charges when the liability is probable and the amount is estimable. Employee termination benefits are accrued at the date management has committed to a plan of termination and affected employees have been notified of their termination date and expected severance benefits.

**Recent Accounting Pronouncements**

***Accounting Standards Update 2016-13***

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. As a smaller reporting company, this ASU and its subsequent updates, is effective for fiscal years beginning after December 15, 2022. 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. We adopted this ASU on January 1, 2020 and the adoption of this standard did not 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. We adopted this ASU on January 1, 2020 and the adoption of this standard did not 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. We adopted this ASU on January 1, 2020 and the adoption of this standard did not have a material impact on our consolidated financial statements.

***Accounting Standards Update 2019-12***

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740). This ASU simplifies the accounting for income taxes by removing certain exceptions and improving consistent application in certain areas of Topic 740. The ASU is effective for annual periods beginning after December 15, 2020 with early adoption permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

## 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, 2 and 3 during the years ended December 31, 2019 and 2018.

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

**Recurring Fair Value Measurements**

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

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| **December 31, 2019** | | | | |
| *Assets* | | | | |
| Money market funds | $ 27,854 | $ - | $ - | $ 27,854 |
| U.S. treasuries | - | 6,517 | - | 6,517 |
| U.S. government agency securities | - | 51,273 | - | 51,273 |
| Corporate debt securities | - | 61,373 | - | 61,373 |
| *Total assets* | $ 27,854 | $ 119,163 | $ - | $ 147,017 |
| *Liabilities* | | | | |
| Warrant liability | $ - | $ - | $ 14,860 | $ 14,860 |
| Sublicense liability | - | - | 6,948 | 6,948 |
| *Total liabilities* | $ - | $ - | $ 21,808 | $ 21,808 |

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| **December 31, 2018** | | | | |
| *Assets* | | | | |
| 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 assets* | $ 44,002 | $ 98,387 | $ - | $ 142,389 |
| *Liabilities* | | | | |
| Sublicense liability | $ - | $ - | $ 6,320 | $ 6,320 |

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.

Warrants were issued in connection with the underwritten public offering in August 2019 and are accounted for as a derivative liability at fair value. See Note 14. The fair value of the warrant liability is estimated using the Black-Scholes model which requires assumptions such as expected term, expected volatility and risk-free interest rate. These assumptions are subjective and require judgement to develop. Expected term is estimated using the full remaining contractual term of the warrants. We determine expected volatility based on our historical common stock price volatility. The warrant liability is classified as a Level 3 instrument as its value is based on unobservable inputs that are supported by little or no market activity.

As of December 31, 2019, we used the following key assumptions to estimate the fair value of warrant liability:

| | |
|---|---|
| Number of shares | 5,841,250 |
| Expected term | 2.1 years |
| Expected volatility | 0.6 |
| Risk-free interest rate | 1.6% |
| Dividend yield | 0% |

The following table provides a summary of changes in the fair value warrant liability for year ended December 31, 2019 (in thousands):

| | |
|---|---|
| Balance at December 31, 2018 | $ - |
| Fair value of warrant liability at issuance date | 7,360 |
| Increase in estimated fair value of warrant liability upon revaluation | 7,500 |
| Balance at December 31, 2019 | $ 14,860 |

As of December 31, 2019, 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 $6.9 million as of December 31, 2019.

## 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 | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| Cash and cash equivalents | $ 39,884 | $ 49,348 | $ 26,584 |
| Restricted cash | 216 | 619 | 629 |
| Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows | $ 40,100 | $ 49,967 | $ 27,213 |

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, 2019** | | | | |
| Cash and cash equivalents: | | | | |
| Cash | $ 4,038 | $ - | $ - | $ 4,038 |
| Money market funds | 27,854 | - | - | 27,854 |
| Corporate debt securities | 7,992 | - | - | 7,992 |
| Total cash and cash equivalents | 39,884 | - | - | 39,884 |
| Marketable securities available-for-sale: | | | | |
| U.S. treasuries | 6,511 | 6 | - | 6,517 |
| U.S. government agency securities | 51,235 | 50 | (12) | 51,273 |
| Corporate debt securities | 53,353 | 28 | - | 53,381 |
| Total marketable securities available-for-sale | 111,099 | 84 | (12) | 111,171 |
| Total cash, cash equivalents and marketable securities | $ 150,983 | $ 84 | $ (12) | $ 151,055 |
| **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 |

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

.

| | December 31, 2019 | |
|---|---|---|
| | Amortized Cost | Estimated Fair Value |
| Mature in one year or less | $ 97,585 | $ 97,662 |
| Mature after one year through two years | 13,514 | 13,509 |
| | $ 111,099 | $ 111,171 |

There were no realized gains or losses from the sale of marketable securities in the years ended December 31, 2019, 2018 and 2017. 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, net (in thousands):

| | December 31 | |
|---|---|---|
| | 2019 | 2018 |
| Raw materials | $ 15,198 | $ 12,111 |
| Work-in-process | 22,890 | 6,562 |
| Finished goods | 3,244 | 349 |
| Total | $ 41,332 | $ 19,022 |

## 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, | |
|---|---|---|
| | 2019 | 2018 |
| Intangible assets | $ 19,773 | $ 19,773 |
| Less accumulated amortization | (17,273) | (8,056) |
| Total | $ 2,500 | $ 11,717 |

We recorded cost of sales - amortization of intangible assets related to capitalized milestone and sublicense payments to Merck, GlaxoSmithKline Biologicals SA ("GSK") and Coley Pharmaceutical Group, Inc. ("Coley") that we capitalized upon or after FDA approval of HEPLISAV-B in November 2017. See Note 10. In 2019, cost of sales – amortization of intangible assets of $9.2 million was related to capitalized Merck payments. In 2018, cost of sales – amortization of intangible assets of $8.1 million, $1.5 million and $1.3 million, were related to capitalized Merck, GSK and Coley payments, respectively. In 2017, cost of sales – amortization of intangible assets of $1.2 million was related to capitalized Coley payment.

At December 31, 2018, intangible assets related to GSK and Coley have been fully-amortized. The remaining intangible asset related to Merck 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 (In years) | December 31, | |
|---|---|---|---|
| | | 2019 | 2018 |
| Manufacturing equipment | 5-14 | $ 11,484 | $ 12,029 |
| Lab equipment | 5-13 | 2,522 | 6,938 |
| Computer equipment | 3 | 5,009 | 5,465 |
| Furniture and fixtures | 3-13 | 1,934 | 1,809 |
| Leasehold improvements | 2-12 | 24,724 | 11,367 |
| Assets in progress | | 4,336 | 2,605 |
| | | 50,009 | 40,213 |
| Less accumulated depreciation and amortization | | (17,987) | (23,149) |
| Total | | $ 32,022 | $ 17,064 |

Depreciation and amortization expense on property and equipment was $8.9 million, $3.6 million and $3.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. Included in depreciation and amortization expense for the year ended December 31, 2019 was accelerated depreciation of $3.0 million related to certain long-lived assets. See Note 17.

## 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, | |
|---|---|---|
| | 2019 | 2018 |
| Payroll and related expenses | $ 6,653 | $ 8,058 |
| Revenue reserve accruals | 3,893 | 1,033 |
| Third party research expenses | 2,308 | 7,819 |
| Third party development expenses | 505 | 1,377 |
| Restructuring liability | 675 | - |
| Other accrued liabilities | 4,888 | 7,468 |
| Total | $ 18,922 | $ 25,755 |

## 9. Commitments and Contingencies

**Leases**

As described in Note 2, we adopted ASC 842 as of January 1, 2019. We evaluated our contracts and have determined that, effective upon the adoption of ASC 842, our operating leases included equipment, office/laboratory and manufacturing facility leases.

We lease our facilities in Emeryville, California and Düsseldorf, Germany.

In July 2019, we entered into a sublease for office space located at 2100 Powell Street, Emeryville, California (the "Powell Street Sublease") and the lease for our former corporate headquarters at 2929 Seventh Street, Berkeley, California was terminated effective August 31, 2019. Under the terms of the Powell Street Sublease, we are leasing 23,976 square feet at the rate of $3.90 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and we are responsible for certain operating expenses and taxes throughout the life of the Powell Street Sublease. The Powell Street Sublease will continue until June 30, 2022. There is no option to extend the sublease term.

On September 17, 2018, we entered into a lease ("Horton Street Master Lease") for office and laboratory space located at 5959 Horton Street, Emeryville, California ("Horton Street Premises"). Under the terms of the Horton Street Master Lease, we are leasing 75,662 square feet at the rate of $4.75 per square foot, paid on a monthly basis, starting on April 1, 2019 ("Commencement Date"). Rent is subject to scheduled annual increases, and we are also responsible for certain operating expenses and taxes throughout the life of Horton Street Master Lease. In connection with the Horton Street Master Lease, we are entitled to a tenant improvement allowance of up to $8.3 million, of which $7.0 million was received through December 31, 2019. The Horton Street Master 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. The optional periods were not included in the lease term used in determining the right-of-use asset or the lease liability as we did not consider it reasonably certain that we would exercise the options. The operating lease right-of-use assets and liabilities on our December 31, 2019 consolidated balance sheets primarily relate to the Horton Street Master Lease.

In connection with the organizational restructuring in May 2019 (see Note 17), we did not occupy the Horton Street Premises and in July 2019, we entered into an agreement to sublease the Horton Street Premises to a third party ("Horton Street Sublease"). Under the terms of the Horton Street Sublease, we are subleasing the entire 75,662 rentable square feet at the rate of $5.50 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and the subtenant ("Subtenant") is responsible for certain operating expenses and taxes throughout the life of the Horton Street Sublease. The Horton Street Sublease will continue until March 31, 2031, unless earlier terminated, concurrent with the term of our Horton Street Master Lease. The Subtenant has no option to extend the sublease term. For the year ended December 31, 2019, we recognized $2.6 million of sublease income included in other income (expense) in our consolidated statements of operations.

Under the terms of the Horton Street Master Lease, rent received from the Subtenant in excess of rent paid to the landlord is shared by paying the landlord 50% of the excess rent. The excess rent is considered a variable lease payment and the total estimated payments are being recognized as additional rent expense on a straight-line basis.

Our lease expense comprises of the following (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Operating lease expense | $ 6,886 | $ 3,953 | $ 2,386 |

Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2019 was $5.5 million and was included in operating cash flows in our consolidated statement of cash flows.

The balance sheet classification of our operating lease liabilities was as follows (in thousands):

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Operating lease liabilities: | | |
| Current portion of lease liabilities (included in other current liabilities) | $ 3,039 | $ - |
| Long-term portion of lease liabilities | 37,845 | - |
| Total operating lease liabilities | $ 40,884 | $ - |

At December 31, 2019, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

| Years ending December 31, | Sublease Income | Operating Lease Liabilities |
|---|---|---|
| 2020 | $ 4,446 | $ 7,023 |
| 2021 | 5,202 | 6,952 |
| 2022 | 5,358 | 6,201 |
| 2023 | 5,519 | 4,950 |
| 2024 | 5,684 | 4,963 |
| Thereafter | 39,600 | 34,560 |
| Total | $ 65,809 | 64,649 |
| Less: | | |
| Present value adjustment | | (23,765) |
| Total | | $ 40,884 |

As of December 31, 2019, the weighted average remaining lease term is 9.7 years and the weighted average discount rate used to determine the operating lease liability was 10.1%.

**Commitments**

On February 20, 2018, we entered into a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. We borrowed $100.0 million under the Loan Agreement at closing and the remaining $75.0 million in March 2019 (collectively, “Term Loans”). 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, 2019, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $178.6 million, net of debt discount of $1.4 million. Included in our total contractual obligations of $187.2 million is the principal amount of $175.0 million, paid-in-kind interest of $5.0 million and the backend facility fee of $7.2 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. See Note 11.

In February 2018, we entered into a sublicense agreement with Merck. Under the agreement, we paid the third and last installment of $7.0 million in February 2020. See Note 10.

As of December 31, 2019, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, totaled $7.6 million.

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, 2019 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, 2019 and 2018.

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, 2019 and 2018.

**Contingencies**

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.

## 10. Collaborative Research, Development and License Agreements

**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. For the year ended December 31, 2019 and 2018, we recognized collaboration revenue of $0.1 million and $1.4 million, respectively. No collaborative revenue was recognized prior to 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, second and third installment of $7.0 million each was paid in February 2018, 2019 and 2020, respectively. The payment in 2020 is classified on the consolidated balance sheets as other current liabilities. In February 2018, we recorded $19.8 million as an intangible asset. At December 31, 2019, the intangible asset, net balance was $2.5 million. See Note 6. The Sublicense Agreement continues to be 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 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 Loan Agreement with CRG Servicing LLC. Net proceeds under the Loan Agreement were $173.3 million. The Term Loans under the Loan Agreement bear interest at a rate equal to 9.5% per annum. At December 31, 2019, the effective interest rate was 10.3%. 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, 2019, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $178.6 million, net of debt discount of $1.4 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.

In August 2019, we entered into a second amendment to the Loan Agreement (the "Second Amendment"). The Second Amendment amended the annual net sales threshold for sales of HEPLISAV-B, revising the twelve-month measurement periods from beginning on January 1 of each year to beginning on July 1 of each year (including 2019) and ending on June 30, 2023. The Second Amendment also revised the fee payable upon partial prepayment or at maturity of the Term Loans from 3% to 4% of the aggregate principal amounts.

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 a twelve-month period revenue requirement starting on July 1, 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 $16.5 million and $8.8 million of interest expense related to the Term Loans during the year ended December 31, 2019 and 2018, respectively.

## 12. Revenue Recognition

Our source of product revenue 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, 2019 and 2018 (in thousands):

| | Balance at Beginning of Period | Provisions related to current period sales | Credit or payments made during the period | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2019: | | | | |
| Accounts receivable reserves(1) | $ 1,272 | $ 11,042 | $ (9,613) | $ 2,701 |
| Revenue reserve accruals(2) | $ 1,033 | $ 6,632 | $ (3,772) | $ 3,893 |
| Year ended December 31, 2018: | | | | |
| Accounts receivable reserves(1) | $ - | $ 3,274 | $ (2,002) | $ 1,272 |
| Revenue reserve accruals(2) | $ - | $ 1,308 | $ (275) | $ 1,033 |

*(1) Reserves are for chargebacks, discounts and other fees.*
*(2) Accruals are for returns, rebates and other fees*

## 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, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| **Basic and diluted net loss per share (in thousands, except per share amounts):** | | | |
| Numerator: | | | |
| Net loss | $ (152,600) | $ (158,899) | $ (95,154) |
| Preferred stock deemed dividend | (3,267) | - | - |
| Net loss allocable to common stockholders | $ (155,867) | $ (158,899) | $ (95,154) |
| Denominator for basic and diluted net loss per share allocable to common stockholders: | | | |
| Weighted-average common shares outstanding | 72,024 | 62,362 | 52,613 |
| Basic and diluted net loss per share allocable to common stockholders | $ (2.16) | $ (2.55) | $ (1.81) |

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, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| **Outstanding securities not included in diluted net loss per share calculation (in thousands):** | | | |
| Stock options and stock awards | 9,789 | 7,344 | 5,981 |
| Series B Convertible Preferred Stock (as converted to common stock) | 4,840 | - | - |
| Warrants | 5,841 | - | - |

## 14. Common Stock

### Common Stock Outstanding

As of December 31, 2019, there were 83,871,119 shares of our common stock outstanding.

In August 2019, we sold (i) 18,525,000 shares of our common stock, par value $0.001 per share, (ii) 4,840 shares of our Series B Preferred Stock, par value $0.001 per share ("Series B Preferred Stock") and (iii) warrants to purchase up to an aggregate of 5,841,250 shares of our common stock in an underwritten public offering (the "Offering"). Each share of common stock was sold together with a warrant to purchase 0.25 shares of common stock, at a combined price of $3.00 per share of common stock and the accompanying warrant. Each share of Series B Preferred Stock was sold together with a warrant to purchase 250 shares of common stock, at a combined price of $3,000 per share and the accompanying warrant. Proceeds from the Offering were approximately $65.6 million, net of issuance costs of $4.5 million.

Investment funds associated with Bain Capital Life Sciences Investors, LLC, or Bain Capital Life Sciences, have purchased approximately $35.0 million of common stock, Series B Preferred Stock and warrants in this Offering at the public offering price. Pursuant to the Offering, (i) Bain Capital Life Sciences Fund, L.P. purchased 6,826,266 shares of common stock, 3,756 shares of Series B Preferred Stock and warrants to purchase 2,645,566 shares of common stock for a total purchase price of approximately $31.7 million and (ii) BCIP Life Sciences Associates, L.P. purchased 698,734 shares of common stock, 384 shares of Series B Preferred Stock and warrants to purchase 270,684 shares of common stock for a total purchase price of approximately $3.2 million. Bain Capital Life Sciences Investors, LLC is the general partner of Bain Life Sciences. The participation by these investors was on the same terms as the other investors in the Offering.

Following the offering, Andrew A. F. Hack, M.D., Ph.D and Managing Director of Bain Capital Life Sciences (a related party), was appointed to our board of directors.

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, 2019, we received net cash proceeds of $13.9 million resulting from sales of 1,386,906 shares of our common stock. As of December 31, 2019, we have $118.6 million remaining under the 2017 ATM Agreement. Subsequent to December 31, 2019 and through March 11, 2020, we sold 2,180,266 shares of common stock for net proceeds of $11.7 million under the 2017 ATM Agreement.

### Preferred Stock Outstanding

As of December 31, 2019, there were 4,840 shares of Series B Preferred Stock outstanding.

Each share of Series B Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting the Series B Preferred Stock into shares of common stock if, as a result of such conversion, the holder and its affiliates would own more than 4.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holders' election to a higher or lower percentage (not to exceed 19.99%) upon 61 days' notice to the Company. In the event of liquidation, dissolution, or winding up, the holder of Series B Preferred Stock will receive payment on shares of Series B Preferred Stock (determined on an as-converted to common stock basis) equal to the amount that would be paid on our common stock. Shares of Series B Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock is required to amend the terms of the Series B Preferred Stock. Holders of Series B Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. The Series B Preferred Stock ranks on parity with our common stock as to distributions of assets upon liquidation, dissolution or winding up. The Series B Preferred Stock may rank senior to, on parity with or junior to any class or series of capital stock created in the future depending upon the specific terms of such future stock issuance.

The fair value of the common stock into which the Series B Preferred Stock is convertible exceeded the allocated purchase price of the Series B Preferred Stock by $3.3 million on the date of issuance, for which we recorded a deemed dividend. We recognized a deemed dividend equal to the number of common stock into which the Series B Preferred Stock is convertible multiplied by the difference between the value of the common stock and the Series B Preferred Stock conversion price per share on the date of issuance, which is the date the stock first became convertible. The dividend was reflected as a one-time, non-cash, deemed dividend to the holders of Series B Preferred Stock on the date of issuance.

**Warrants**

As of December 31, 2019, the following common stock warrants were outstanding:

| Warrants Issuance Date | Shares Issuable (in thousands) | Expiration Date | Exercise Price per Share | Outstanding as of December 31, 2019 (in thousands) |
|---|---|---|---|---|
| August 12, 2019 | 5,841 | February 12, 2022 | $ 4.50 | 5,841 |

Warrants were exercisable upon issuance. The holder is prohibited from exercising these warrants if, as a result of such exercise, the holder and its affiliates, would own more than 4.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holders' election to a higher or lower percentage (not to exceed 19.99%) upon 61 days' notice to the Company.

The warrants contain provisions that may obligate us to repurchase them for an amount that does not represent fair value in the event of a change of control. Due to this provision, the warrants do not meet the criteria to be considered indexed to our own stock. Accordingly, we recorded the warrants as a derivative liability at fair value of $7.4 million on the issuance date, which was estimated using the Black-Scholes model.

The warrants will be revalued at each reporting period using the Black-Scholes model and the change in the fair value of the warrants will recognized as other income (expense) in the consolidated statements of operations. At December 31, 2019, the estimated fair value of warrant liability was $14.9 million. For year ended December 31, 2019, we recognized the $7.5 million increase in the estimated fair value as a loss on warrant liability in other income (expense), net in our consolidated statements of operations.

## 15. Equity Plans and Stock-Based Compensation

**Equity Plans**

Our 2018 Equity Incentive Plan (the "2018 EIP") is intended to be the successor to and continuation of 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 our employees and directors.

On May 30, 2019, our stockholders approved an amendment to 2018 Equity Incentive Plan (the "Amended 2018 EIP") to, among other things, increase the aggregate number of shares of common stock authorized for issuance by 2,300,000. Under the Amended 2018 EIP, the aggregate number of shares of our common stock that may be issued to employees and directors (subject to adjustment for certain changes in capitalization) is 14,917,869.

The Amended 2018 EIP is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the Amended 2018 EIP have a term of 7 years unless earlier terminated by the Board of Directors. As of December 31, 2019, there were 3,308,216 shares of common stock reserved for issuance under the Amended 2018 EIP.

Activity under our stock plans is set forth below:

| | Shares Underlying Outstanding Options (in thousands) | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balance at December 31, 2018 | 5,750 | $ 18.20 | | |
| Options granted | 3,747 | 6.88 | | |
| Options exercised | (10) | 5.75 | | |
| Options cancelled: | | | | |
| Options forfeited (unvested) | (1,278) | 12.54 | | |
| Options expired (vested) | (203) | 16.52 | | |
| Balance at December 31, 2019 | 8,006 | $ 13.86 | 4.47 | $ 2,125 |
| Vested and expected to vest at December 31, 2019 | 7,729 | $ 14.11 | 4.40 | $ 1,954 |
| Exercisable at December 31, 2019 | 4,531 | $ 18.37 | 3.09 | $ 3 |

The total intrinsic value of stock options exercised during the years ended December 31, 2019, 2018 and 2017 was $26,000, $0.2 million and $0.9 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, 2019, 2018 and 2017 was $19.5 million, $8.1 million and $13.0 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, 2019, and activities during 2019 are summarized as follows:

| | Number of Shares (In thousands) | Weighted-Average Grant-Date Fair Value |
|---|---|---|
| Non-vested as of December 31, 2018 | 1,594 | $ 8.82 |
| Granted | 1,823 | 8.80 |
| Vested | (970) | 6.79 |
| Forfeited | (663) | 10.81 |
| Non-vested as of December 31, 2019 | 1,784 | $ 9.16 |

Stock-based compensation expense related to restricted stock units was approximately $9.1 million for the year ended December 31, 2019. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2019, based on our stock price on that date, was $10.2 million.

The total fair value of restricted stock units vested during the years ended December 31, 2019, 2018 and 2017 was $7.9 million, $19.4 million and $1.2 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, 2019, approximately 155,000 shares underlying stock options and approximately 89,000 restricted stock unit awards with performance-based vesting criteria were outstanding. All of the awards with performance-based vesting criteria were deemed probable as of December 31, 2019. We recognized stock-based compensation expense for awards with performance-based vesting criteria during the years ended December 31, 2019, 2018 and 2017 of $0.5 million, $1.9 million and $0.3 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 | | | Employee Stock Purchase Plan | | |
|---|---|---|---|---|---|---|
| | Year Ended December 31, | | | Year Ended December 31, | | |
| | 2019 | 2018 | 2017 | 2019 | 2018 | 2017 |
| Weighted-average fair value | $ 4.58 | $ 10.75 | $ 8.27 | $ 2.72 | $ 8.30 | $ 3.05 |
| Risk-free interest rate | 2.1% | 2.5% | 1.9% | 1.9% | 2.4% | 1.0% |
| Expected life (in years) | 4.5 | 4.2 | 4.5 | 1.2 | 1.3 | 1.2 |
| Expected Volatility | 0.9 | 0.8 | 0.9 | 0.7 | 1.1 | 1.0 |

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. Stock-based compensation cost for the year ended December 31, 2019 includes incremental cost of $4.1 million for accelerated vesting of stock awards and extension of exercise period of stock options in connection with the retirement of our Chief Executive Officer. See Note 17.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Employees and directors stock-based compensation expense | $ 25,456 | $ 23,478 | $ 14,917 |

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Research and development | $ 8,058 | $ 9,604 | $ 7,827 |
| Selling, general and administrative | 10,224 | 11,761 | 7,090 |
| Cost of sales - product | 1,088 | 1,354 | - |
| Inventory | 1,964 | 759 | - |
| Restructuring | 4,122 | - | - |
| Total | $ 25,456 | $ 23,478 | $ 14,917 |

As of December 31, 2019, 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 $28.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years. Additionally, as of December 31, 2019, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $0.1 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 two-year 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, 2019, employees have acquired 122,117 shares of our common stock under the Purchase Plan and 450,917 shares of our common stock remained available for future purchases under the Purchase Plan.

As of December 31, 2019, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan amounted to $0.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 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 $0.3 million for the year ended December 31, 2019 and approximately $0.2 million for each of the years ended December 31, 2018 and 2017.

## 17. Restructuring

On May 23, 2019, we implemented a strategic organizational restructuring, principally to align our operations around our vaccine business and significantly curtail further investment in our immuno-oncology business. In connection with the restructuring, we reduced our workforce by approximately 80 positions, or approximately 36%, of U.S.-based personnel. Also, in connection with the restructuring, our Chief Executive Officer, also a member of the Board of Directors (the "Board"), submitted notice of his retirement from the Company and the Board, effective August 1, 2019. As of December 31, 2019, we have completed our restructuring activities and all costs have been incurred.

The major components of our restructuring costs are summarized as follows (in thousands):

| Components of Restructuring Costs | Total Restructuring Costs Expected to be Incurred | Restructuring Costs Incurred for the Year Ended December 31, 2019 | Remaining to be Incurred |
|---|---|---|---|
| Severance and other termination benefits | $ 6,277 | $ 6,277 | $ - |
| Stock-based compensation expense (a) | 4,122 | 4,122 | - |
| Accelerated depreciation | 2,957 | 2,957 | - |
| Total restructuring cost | $ 13,356 | $ 13,356 | $ - |

*(a) As a result of accelerated vesting of stock awards and the extension of exercise period of stock options*

The outstanding restructuring liabilities are included in accrued liabilities on the consolidated balance sheets. As of December 31, 2019, the components of the restructuring liabilities were as follows (in thousands):

| | Severance and Other Termination Benefits |
|---|---|
| Balance at December 31, 2018 | $ - |
| Severance and other termination benefits | 6,277 |
| Cash payments or settlements | (5,602) |
| Balance at December 31, 2019 | $ 675 |

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, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| U.S. | $ (154,605) | $ (160,032) | $ (95,898) |
| Non U.S. | 2,005 | 1,133 | 744 |
| Total | $ (152,600) | $ (158,899) | $ (95,154) |

No income tax expense was recorded for the years ended December 31, 2019, 2018 and 2017 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, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Income tax benefit at federal statutory rate | $ (32,046) | $ (33,366) | $ (32,352) |
| State tax | (3,153) | (5,591) | (4,482) |
| Business credits | (1,757) | (3,065) | (1,960) |
| Uncertain tax positions | 5,426 | - | - |
| Deferred compensation charges | 4,600 | (1,165) | 3,823 |
| Change in valuation allowance | 22,715 | 43,134 | (109,165) |
| Rate change | - | - | 86,943 |
| Net operating loss and tax credit limitation | - | - | 56,962 |
| Section 162(m) limitation | 2,439 | - | - |
| Mark-to-market of warrants | 1,575 | - | - |
| Other | 201 | 53 | 231 |
| Total income tax expense | $ - | $ - | $ - |

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

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Deferred tax assets:** | | |
| Net operating loss carry forwards | $ 207,385 | $ 178,730 |
| Research tax credit carry forwards | 27,883 | 34,064 |
| Accruals and reserves | 17,312 | 10,137 |
| Capitalized research costs | 256 | 943 |
| Other | 2,437 | 1,147 |
| Total deferred tax assets | 255,273 | 225,021 |
| Less valuation allowance | (247,092) | (224,746) |
| Net deferred tax assets | 8,181 | 275 |
| **Deferred tax liabilities:** | | |
| Fixed assets | (275) | (275) |
| Operating lease right-of-use assets | (7,906) | - |
| Total deferred tax liabilities | (8,181) | (275) |
| 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 $22.3 million and $40.4 million for the years ended December 31, 2019 and 2018, respectively, due to an increase in our deferred tax assets.

As of December 31, 2019, we had federal net operating loss carryforwards of approximately $887.3 million, which will begin to expire in the year 2020 and federal research and development tax credits of approximately $21.7 million, which expire in the years 2020 through 2039.

As of December 31, 2019, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $318.3 million, which expire in the years 2020 through 2039, and California state research and development tax credits of approximately $19.6 million, which do not expire.

As of December 31, 2019, we had net operating loss carryforwards for foreign income tax purposes of approximately $9.0 million, which do not expire.

**Uncertain Income Tax positions**

The total amount of unrecognized tax benefits was $10.3 million and $1.2 million as of December 31, 2019 and 2018, respectively. 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, 2018 | $ (1,229) |
| Tax positions related to the current year | |
| Additions | (439) |
| Reductions | - |
| Tax positions related to the prior year | |
| Additions | (8,654) |
| Reductions | - |
| Balance at December 31, 2019 | $ (10,322) |

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2019, 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, 2019. 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 have not completed an analysis and a limitation calculation has not been performed subsequent to the period ending December 31, 2018. Due to equity issuances in 2019 and changes in ownership of our common stock, we believe that our net operating losses and tax credits in the future may be further limited.

We are subject to income tax examinations for U.S. federal and state income taxes from 2000 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, 2019 | | | |
|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 |
| Total revenues | $ 5,773 | $ 8,301 | $ 10,575 | $ 10,570 |
| Net loss | $ (39,672) | $ (42,713) | $ (33,459) | $ (36,756) |
| Net loss allocable to common stockholders | $ (39,672) | $ (42,713) | $ (36,726) | $ (36,756) |
| Net loss per share allocable to common stockholders - basic and diluted | $ (0.62) | $ (0.66) | $ (0.49) | $ (0.44) |
| Weighted average shares used to compute basic and diluted net loss per share allocable to common stockholders | 63,778 | 65,088 | 75,106 | 83,868 |

| | 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) |
| Net loss per share - basic and diluted | $ (0.63) | $ (0.63) | $ (0.65) | $ (0.64) |
| Weighted average shares used to compute basic and diluted net loss per share | 61,744 | 62,346 | 62,650 | 62,694 |

**20. Subsequent Event**

On March 11, 2020, we entered into a warrant exchange agreement with Bain Capital Life Sciences Fund, L.P. and BCIP Life Sciences Associates, L.P. (together, “Bain Life Sciences”) pursuant to which we agreed that we would, upon future notice from Bain Life Sciences, to exchange all or a portion of the common stock warrants held by Bain Life Sciences for warrants to purchase a new Series C convertible preferred stock. Each share of Series C convertible preferred stock would be convertible into 1,000 shares of common stock, with a conversion price of $4.50 and would have substantially identical rights to, our Series B Convertible Preferred Stock.

## 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, 2019. 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019 and the related notes of the Company and our report dated March 11, 2020 expressed an unqualified opinion thereon.

**Basis for Opinion**

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

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

**Definition and Limitations of Internal Control Over Financial Reporting**

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

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

/s/ Ernst & Young LLP
San Francisco, California
March 11, 2020

**(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

In August 2019, Bain Capital Life Sciences Fund, L.P. and BCIP Life Sciences Associates, L.P. (together, "Bain Life Sciences") acquired shares of our common stock and Series B convertible preferred stock and warrants to purchase shares of our common stock in an underwritten public offering. Bain Capital Life Sciences Investors, LLC is the general partner of Bain Life Sciences. Andrew A. F. Hack, M.D., Ph.D., a managing director of Bain Capital Life Sciences Investors, LLC, is a director of Dynavax.

On March 11, 2020, we entered into a registration rights agreement with Bain Life Sciences, pursuant to which we agreed, subject to certain exceptions, to register all of the shares of our common stock and Series B convertible preferred stock, and warrants to purchase shares of our common stock, held by Bain Life Sciences as of the date of the registration rights agreement. We have agreed to provide Bain Life Sciences with customary indemnification in in connection with the registration and sale of Bain Life Sciences' securities pursuant to the registration rights agreement.

On March 11, 2020, we also entered into a warrant exchange agreement with Bain Life Sciences pursuant to which we agreed that we would, upon future notice from Bain Life Sciences (and subject to certain other conditions), exchange all or a portion of the common stock warrants held by Bain Life Sciences for warrants to purchase a new Series C convertible preferred stock. Such preferred warrants would be exercisable for a number of shares of Series C convertible preferred stock equal to (x) the number of shares of common stock for which the outstanding common warrants then remain exercisable, divided by (y) 1,000. In connection with such exchange, if any, we would be obligated to file a certificate of designation to specify the powers, preferences, rights, qualifications, limitations and restrictions of the Series C convertible preferred stock. The Series C certificate of designation will provide that each share of Series C convertible preferred stock would be convertible into 1,000 shares of common stock, with a conversion price of $4.50, and would be on parity with, and would otherwise have substantially identical rights to, our Series B convertible preferred stock. Our obligations under the warrant exchange agreement also include the execution of a registration rights agreement, upon request of Bain Life Sciences, concurrent with the warrant exchange, if any, pursuant to which we would register the exchange securities in a manner substantially similar to the registration rights agreement described above.

The preferred warrants to be issued in the exchange, if any, will not be registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws. We will rely on the exemption from the registration requirements of the Securities Act provided under Section 3(a)(9) thereof.

## 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 “Delinquent Section 16(a) Reports” in our Definitive Proxy Statement in connection with the 2020 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, 2019.

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, 2100 Powell Street, Suite 900, Emeryville, CA 94608, (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 Overview,” “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 Related Parties” and “Independence of the Board of Directors” in the Proxy Statement.

### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

## PART IV

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(a) Documents filed as part of this report:**

**1. Financial Statements**

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

**2. Financial Statement Schedules**

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

**(b) Exhibits**

| | | Incorporated by Reference | | | | |
|---|---|---|---|---|---|---|
| **Exhibit Number** | **Document** | **Exhibit Number** | **Filing** | **Filing Date** | **File No.** | **Filed Herewith** |
| 3.1 | Sixth Amended and Restated Certificate of Incorporation | 3.1 | S-1/A | February 5, 2004 | 333-109965 | |
| 3.2 | Amended and Restated Bylaws | 3.8 | 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 | |
| 3.9 | Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation | 3.1 | 8-K | July 31, 2017 | 001-34207 | |

| Exhibit Number | Document | Incorporated by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Exhibit Number | Filing | Filing Date | File No. | |
| 3.10 | Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock | 3.1 | 8-K | August 8, 2019 | 001-34207 | |
| 4.1 | Description of Capital Stock | | | | | X |
| 4.2 | Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10 above | | | | | |
| 4.3 | Form of Specimen Common Stock Certificate | 4.2 | S-1/A | January 16, 2004 | 333-109965 | |
| 4.4 | Form of Warrant to Purchase Common Stock | 4.1 | 8-K | August 8, 2019 | 001-34207 | |
| 10.1 | 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 | |
| 10.2+ | 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 | |
| 10.3+ | Amended and Restated 2014 Employee Stock Purchase Plan | 99.4 | S-8 | June 1, 2016 | 333-211747 | |
| 10.4+ | Form of Amended and Restated Management Continuity and Severance Agreement between the Company and certain of its executive officers | 10.2 | 10-Q | August 7, 2019 | 001-34207 | |
| 10.5 | Sales Agreement, dated November 3, 2017, between the Company and Cowen and Company, LLC | 10.1 | 10-Q | November 3, 2017 | 001-34207 | |
| 10.6+ | 2017 Inducement Award Plan | 10.1 | 8-K | November 30, 2017 | 001-34207 | |
| 10.7† | 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 | |
| 10.8† | Supply Agreement, dated November 2, 2016, between Company and Becton, Dickinson and Company | 10.34 | 10-K | March 8, 2018 | 001-34207 | |
| 10.9† | Supply Agreement, dated October 1, 2012, between Company and Nitto Denko Avecia, Inc. | 10.35 | 10-K | March 8, 2018 | 001-34207 | |
| 10.10† | Supply Agreement, dated July 27, 2016, between Company and West Pharmaceutical Services, Inc. | 10.36 | 10-K | March 8, 2018 | 001-34207 | |

| Exhibit Number | Document | Incorporated by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Exhibit Number | Filing | Filing Date | File No. | |
| 10.11+ | Amended and Restated 2004 Non-Employee Director Equity Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, as amended. | 10.1 | 10-Q | May 9, 2018 | 001-34207 | |
| 10.12 | 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 | |
| 10.13+ | Amended and Restated 2018 Equity Incentive Plan | 10.1 | 10-Q | August 7, 2019 | 001-34207 | |
| 10.14+ | 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 | |
| 10.15+ | Form of Option Grant Notice and Option Agreement under the 2018 Equity Incentive Plan | 10.3 | 8-K | June 1, 2018 | 001-34207 | |
| 10.16 | Office/Laboratory Lease, dated September 17, 2018, between the Company and Emery Station West, LLC | 10.1 | 10-Q | November 6, 2018 | 001-34207 | |
| 10.17+ | Chief Executive Officer Letter, dated December 13, 2019, between the Company and Ryan Spencer | | | | | X |
| 10.18+ | President and Chief Operating Officer Letter, dated December 13, 2019, between the Company and David Novak | | | | | X |
| 10.19+ | Form of Indemnification Agreement | 10.1 | 10-Q | November 7, 2019 | 001-34207 | |
| 10.20 | Sublease, by and between Dynavax Technologies Corporation and MedAmerica, Inc. (d/b/a Vituity), dated July 2, 2019 | 10.2 | 10-Q | November 7, 2019 | 001-34207 | |
| 10.21 | Sublease, by and between Dynavax Technologies Corporation and Zymergen Inc., dated July 12, 2019 | 10.3 | 10-Q | November 7, 2019 | 001-34207 | |
| 10.22 | Amendment No. 2 to Term Loan Agreement and Fee Letter, by and among Dynavax Technologies Corporation, CRG Partners III L.P., CRG Partners III–Parallel Fund “A” L.P. and CRG Servicing LLC | 10.4 | 10-Q | November 7, 2019 | 001-34207 | |
| 10.23+ | Dynavax Technologies Corporation U.S. Annual Bonus Plan | | | | | X |
| 21.1 | List of Subsidiaries | | | | | X |

| Exhibit Number | Document | Incorporated by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Exhibit Number | Filing | Filing Date | File No. | |
| 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 | Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| EX—101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| EX—101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| EX—101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase |
| EX—101.LAB | Inline XBRL Taxonomy Extension Labels Linkbase Document |
| EX—101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |

| | |
|---|---|
| EX—104 | The cover page for the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, has been formatted in Inline XBRL |

† 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 Emeryville, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ RYAN SPENCER

**Ryan Spencer**
**Chief Executive Officer**
**(Principal Executive Officer)**

Date: March 11, 2020

By: /s/ MICHAEL OSTRACH

**Michael Ostrach**
**Chief Financial Officer**
**(Principal Financial Officer)**

Date: March 11, 2020

By: /s/ DAVID JOHNSON

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

Date: March 11, 2020

| Signature | Title | Date |
|---|---|---|
| /s/ RYAN SPENCER<br>**Ryan Spencer** | Chief Executive Officer<br>*(Principal Executive Officer)* | March 11, 2020 |
| /s/ MICHAEL OSTRACH<br>**Michael Ostrach** | Chief Financial Officer<br>*(Principal Financial Officer)* | March 11, 2020 |
| /s/ DAVID JOHNSON<br>**David Johnson** | Vice President, Chief Accounting Officer<br>*(Principal Accounting Officer)* | March 11, 2020 |
| /s/ FRANCIS R. CANO<br>**Francis R. Cano, Ph.D.** | Director | March 11, 2020 |
| /s/ ANDREW HACK<br>**Andrew Hack, M.D., Ph.D.** | Director | March 11, 2020 |
| /s/ DANIEL L. KISNER<br>**Daniel L. Kisner, M.D.** | Director | March 11, 2020 |
| /s/ ARNOLD L. ORONSKY<br>**Arnold L. Oronsky, Ph.D.** | Director | March 11, 2020 |
| /s/ PEGGY V. PHILLIPS<br>**Peggy V. Phillips** | Director | March 11, 2020 |
| /s/ NATALE S. RICCIARDI<br>**Natale S. Ricciardi** | Director | March 11, 2020 |

**Exhibit 4.1**

# DESCRIPTION OF CAPITAL STOCK

*References herein to "Dynavax," "our," "we," "us" and the "Company" refer only to Dynavax Technologies Corporation.*

## General

Our authorized capital stock consists of 139,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share, 4,840 shares of which have been designated as Series B Convertible Preferred Stock. Our common stock is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The following summary description is qualified entirely by reference to the applicable provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law, or Delaware Law. Our certificate of incorporation and our bylaws are incorporated by reference as exhibits to this Annual Report on Form 10-K to which this Description of Capital Stock is an exhibit.

## Common Stock

***Voting Rights.*** Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

***Dividends.*** Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

***Liquidation.*** In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

***Rights and Preferences.*** Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate in the future.

## Preferred Stock

***General.*** Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or the rules of any stock exchange or market on which our securities are then traded), to designate and issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, voting powers, preferences and other rights of the shares of each wholly unissued series, and any qualifications, limitations or restrictions thereof, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon. Preferred stock can also be issued quickly with terms that could have the effect of delaying, deterring or preventing a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

***Series B Convertible Preferred Stock***

The following summary of certain terms and provisions of the Series B Convertible Preferred Stock is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in our certificate of designation of preferences, rights and limitations of Series B Convertible Preferred Stock incorporated by reference as exhibit to this Annual Report on Form 10-K.

*Rank.* The Series B Convertible Preferred Stock rank:

- on parity with all of our common stock;
- senior to any class or series of our capital stock created specifically ranking by its terms junior to the Series B Convertible Preferred Stock;
- on parity with any class or series of our capital stock created specifically ranking by its terms on parity with the Series B Convertible Preferred Stock;
- junior to any class or series of our capital stock created specifically ranking by its terms senior to the Series B Convertible Preferred Stock;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

*Conversion*. Each share of the Series B Convertible Preferred Stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences) at any time at the option of the holder, provided that the holder is prohibited from converting the Series B Convertible Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding; provided, further, that a holder may, upon written notice to us, elect to increase or decrease the beneficial ownership limitation, with any increase to be effective only after 61 days from delivery of such notice.

*Liquidation Preference*. In the event of our liquidation, dissolution, or winding up, holders of the Series B Convertible Preferred Stock have the right to receive a payment equal to the amount that would be paid on the common stock underlying the Series B Convertible Preferred Stock, determined on an as-converted basis.

*Voting Rights.* The shares of Series B Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Convertible Preferred Stock is required to amend the terms of the Series B Convertible Preferred Stock.

*Dividends.* The shares of Series B Convertible Preferred Stock are not entitled to receive any dividends, except to the extent that dividends are paid on our common stock, in which case the holders of the Series B Convertible Preferred Stock will be entitled to participate in such dividends on an as-converted basis.

*Redemption*. The shares of Series B Convertible Preferred Stock are not entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

*Fundamental Transaction.* If a Fundamental Transaction (as more particularly defined in the certificate of designation of preferences, rights and limitations of Series B Convertible Preferred Stock) occurs while any shares of the Series B Convertible Preferred Stock are outstanding, then upon any subsequent conversion of the Series B Convertible Preferred Stock, each holder has the right to receive, in lieu of the right to receive the shares of our common stock that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had, immediately prior to such Fundamental Transaction, converted its shares of Series B Convertible Preferred Stock into common stock. If holders of our common stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then each holder of the Series B Convertible Preferred Stock shall be given the same choice as to the consideration it receives upon any conversion of the Series B Convertible Preferred Stock following such Fundamental Transaction.

**Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Bylaws and Delaware Law**

***Certificate of Incorporation and Bylaws***

Our certificate of incorporation and bylaws provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of our directors due to be elected at each annual meeting of our stockholders. In addition, our certificate of incorporation provides that vacancies on our board of directors resulting from death, resignation, disqualification, removal or other causes may be filled by the affirmative vote of a majority of the remaining directors in office, even if less than a quorum, and that newly created directorships shall be filled by the affirmative vote of a majority of the directors then in office, even if less than a quorum, unless our board of directors determines otherwise. Our bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing, and that only the chairman of our board, our president, our secretary or a majority of the authorized number of directors may call a special meeting of stockholders. Our certificate of incorporation requires a 66-2/3% stockholder vote for the amendment, repeal or modification of certain provisions of our certificate of incorporation relating to, among other things, the classification of our board of directors and filling of vacancies on our board of directors. Our certificate of incorporation and bylaws also require a 66-2/3% stockholder vote for the stockholders to adopt, amend or repeal certain provisions of our bylaws relating to stockholder proposals at annual meetings, director nominees and the number and term of office of directors. Our board of directors also has the unilateral authority to repeal, alter or amend our bylaws or adopt new bylaws by unanimous written consent or at a meeting by the affirmative vote of a majority of the directors.

The combination of the classification of our board of directors, the lack of cumulative voting and the 66-2/3% stockholder voting requirements will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change of our control.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or in our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and in the policies they implement, and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

***Section 203 of Delaware Law***

We are subject to Section 203 of Delaware Law, or Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition involving the interested stockholder (in one transaction or a series of transactions) of assets of the corporation having an aggregate market value equal to 10% or more of the aggregate market value of either all of the assets of the corporation or its outstanding stock;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect, directly or indirectly, of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit, directly or indirectly (except proportionately as a stockholder of such corporation), of any loans, advances, guarantees, pledges or other financial benefits, other than certain benefits set forth in Section 203, provided by or through the corporation.

Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

December 13, 2019

Mr. Ryan Spencer

Re: Appointment as Chief Executive Officer

On behalf of the Board of Directors (the "Board") of Dynavax Technologies Corporation (the "Company"), I am pleased to confirm the terms of your appointment to the position of Chief Executive Officer (CEO), effective December 16, 2019, on the terms set forth in this letter agreement (the "Agreement").

In your position as CEO of the Company, you will report to the Board. You will have those duties and responsibilities as customary for a CEO and as may be directed by the Board. You will be based in the Company's corporate headquarters in Emeryville, California, and your position will entail business travel. On or promptly after the commencement of your service as CEO, the Company will use its best efforts to appoint you as a member of the Board. In the event of the termination of your employment for any reason (whether at your request or the Company's request), or your removal from the position of CEO, you agree to promptly resign as a member of the Board, effective no later than such termination or removal date. During your employment with the Company, you will devote your full-time best efforts to the business of the Company.

Effective December 16, 2019, your annual base salary will be $515,000, less standard payroll deductions and tax withholdings. You will be paid your base salary on a semi-monthly basis, on the Company's normal payroll schedule. You will continue your eligibility to participate in the Company's standard employee benefits (pursuant to the terms and conditions of the benefit plans and applicable policies).

The Board will review your base salary for potential modification on an annual basis, starting in 2021, provided that, the Board may not decrease your base salary except proportionately in connection with an across-the-board decrease of base salaries applicable to all senior executives of the Company.

Your annual incentive bonus target for the 2020 plan year will be sixty percent (60%) of your base salary, as determined within the discretion of the Board. The incentive bonus will be based upon performance of the Company within the discretion of the Board. Following the close of each calendar year, the Board will determine whether you have earned an incentive bonus, and the amount of any incentive bonus. Generally, incentive bonuses are paid in the first quarter of the following year. You must be an employee in good standing on the bonus payment date to be eligible to receive a bonus. Your annual incentive bonus is not guaranteed.

The Company will grant you a stock option under the Company's 2018 Equity Incentive Plan (the "Equity Plan") to purchase 400,000 shares of the Common Stock of the Company, with an exercise price equal to the fair market value of the Common Stock on the date of grant. This stock option is subject to all the terms and conditions set forth in the applicable award agreement and the Equity Plan. Your stock option grant of 400,000 shares of the Common Stock of the Company will vest as follows: one-third (1/3) % of the Shares subject to the Option shall vest twelve months after the Vesting Commencement Date, and 1/36 of the Shares subject to the Option shall vest on the last day of each month, provided that vesting shall cease upon termination of your continuous service to the Company. In addition to the vesting schedules discussed above, the Options will be subject to accelerated vesting under certain circumstances as will be provided in an Amended Management Continuity and Severance Agreement ("MCSA"), further referenced below, that will be entered into between you and the Company.

You will be expected to continue to abide by Company rules and regulations, as well as the Dynavax Code of Business Conduct and Ethics, and the Company's standard Proprietary Information and Inventions Agreement, which prohibits unauthorized use or disclosure of the Company's proprietary information.

Throughout your employment with the Company, you may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of your duties hereunder or present a conflict of interest with the Company. Subject to the restrictions set forth herein, and with prior written disclosure to and consent of the Board, you may serve as a director of other corporations and may devote a reasonable amount of your time to other types of business or public activities (including charitable activities) not expressly mentioned in this paragraph. The Board may rescind such consent, if the Board determines, in its sole discretion, that such activities compromise or threaten to compromise the Company's business interests or conflict with your duties to the Company.

During your employment by the Company, you will not, without the express written consent of the Board, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venture, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that you may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (but without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

Your employment relationship with the Company is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company; and the Company may terminate your employment at any time with or without cause or prior notice.

By signing this letter, you represent that you are able to perform your job duties within these guidelines.

You will be eligible for certain severance benefits in connection with the termination of your employment under certain circumstances, as will be set forth in the above referenced MCSA.

This Agreement may be executed in counterparts which shall be deemed to be part of one original, and signatures transmitted by PDF file shall be equivalent to original signatures.

We are delighted to appoint you to this position. The Board looks forward to a productive and enjoyable work relationship.

Sincerely,

/s/ Peggy Phillips
Peggy Phillips
Director and Chair of the Compensation Committee

Reviewed, Understood, and Accepted:

/s/ Ryan Spencer
Ryan Spencer December 13, 2019

December 13, 2019

Mr. David Novack

Re: Promotion to President and Chief Operating Officer

Dear David:

On behalf of the Board of Directors (the "Board") of Dynavax Technologies Corporation (the "Company"), I am pleased to confirm the terms of your appointment to the position of President and Chief Operating Officer (COO), effective December 16, 2019, on the terms set forth in this letter agreement (the "Agreement").

In your position as President & COO of the Company, you will report to Ryan Spencer, Chief Executive Officer. You will have those duties and responsibilities as customary for a President & COO and as may be directed by your direct Manager. You will be based in the Company's corporate headquarters in Emeryville, California, and your position will entail business travel. During your employment with the Company, you will devote your full-time best efforts to the business of the Company.

Effective December 16, 2019, your annual base salary will be $495,000, less standard payroll deductions and tax withholdings. You will be paid your base salary on a semi-monthly basis, on the Company's normal payroll schedule. You will continue your eligibility to participate in the Company's standard employee benefits (pursuant to the terms and conditions of the benefit plans and applicable policies).

The Board will review your base salary for potential modification on an annual basis, starting in 2021, provided that, the Board may not decrease your base salary except proportionately in connection with an across-the-board decrease of base salaries applicable to all senior executives of the Company.

Your annual incentive bonus target for the 2020 plan year will be 55 percent of your base salary, as determined within the discretion of the Board. The incentive bonus will be based upon performance of the Company within the discretion of the Board. Following the close of each calendar year, the Board will determine whether you have earned an incentive bonus, and the amount of any incentive bonus. Generally, incentive bonuses are paid in the first quarter of the following year. You must be an employee in good standing on the bonus payment date to be eligible to receive a bonus. Your annual incentive bonus is not guaranteed.

The Company will grant you a stock option under the Company's 2018 Equity Incentive Plan (the "Equity Plan") to purchase 200,000 shares of the Common Stock of the Company, with an exercise price equal to the fair market value of the Common Stock on the date of grant. This stock option is subject to all the terms and conditions set forth in the applicable award agreement and the Equity Plan. Your stock option grant of 200,000 shares of the Common Stock of the Company will vest as follows: one-third (1/3) % of the Shares subject to the Option shall vest twelve months after the Vesting Commencement Date, and 1/36 of the Shares subject to the Option shall vest on the last day of each month, provided that vesting shall cease upon termination of your continuous service to the Company. In addition to the vesting schedules discussed above, the Options will be subject to accelerated vesting under certain circumstances as will be

provided in the Amended Management Continuity and Severance Agreement ("MCSA"), further referenced below, between you and the Company.

You will be expected to continue to abide by Company rules and regulations, as well as the Dynavax Code of Business Conduct and Ethics, and the Company's standard Proprietary Information and Inventions Agreement, which prohibits unauthorized use or disclosure of the Company's proprietary information.

Your employment relationship with the Company is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company; and the Company may terminate your employment at any time with or without cause or prior notice.

By signing this letter, you represent that you are able to perform your job duties within these guidelines.

You will be eligible for certain severance benefits in connection with the termination of your employment under certain circumstances, as will be set forth in the MCSA.

This Agreement may be executed in counterparts which shall be deemed to be part of one original, and signatures transmitted by PDF file shall be equivalent to original signatures.

We are delighted to appoint you to this position. The Board looks forward to a productive and enjoyable work relationship.

Sincerely,

/s/ Peggy Phillips
Peggy Phillips
Director and Chair of the Compensation Committee

Reviewed, Understood, and Accepted:

/s/ David Novack
David Novack Date: December 13, 2019

**Exhibit 10.23**

**Dynavax Technologies Corporation**

**U.S. Annual Bonus Plan**

## Purpose and Effective Date

Dynavax Technologies Corporation ("*Dynavax*" or the "*Company*") has established this Annual Bonus Plan (the "*Bonus Plan*") to align employee performance with annual corporate and individual goals and to reward the achievement of such goals during a performance year. The Bonus Plan will become effective on January 1, 2020, beginning with the 2020 performance year.

## Administration

The Board and the Compensation Committee shall have the sole discretion and authority to administer and interpret the Bonus Plan. The decisions of the Board and the Compensation Committee shall in every case be final and binding on all persons having an interest in the Bonus Plan. The Board and Compensation Committee may, with respect to any performance year, determine the level of achievement of corporate and individual goals or choose not to fund the Bonus Plan, all at its sole discretion. Notwithstanding the foregoing, the Bonus Plan may be administered by the Company's management if the Board or Compensation Committee delegates such authority, and in such event, the Company's management shall have the discretion and authority to administer and interpret such aspects of the Bonus Plan, and the decisions of the Company's management shall in such cases be final and binding.

## Eligibility

In order to be eligible to participate in the Bonus Plan for a performance year, an individual must (a) be a Dynavax employee in the United States who works at least 20 hours per week, including Executive Officers, (b) have become an employee of Dynavax before or on the first business day in October of such performance year, and (c) not be a participant in Dynavax's Sales Incentive Compensation program.

Because Dynavax intends to incentivize successful Participants to remain with Dynavax, Participants must be employed by Dynavax on the day payment is made to earn and be eligible for a bonus payment under the Bonus Plan.

## Application of Bonus Targets

Dynavax sets a "*Bonus Target*" for each Participant measured as a percentage of the Participant's Base Salary for the applicable performance year as set forth in the Annual Criteria.

Unless determined otherwise, Bonus Targets are applied as follows:

- If a Participant is promoted during a performance year and the Participant's Bonus Target percentage increases in connection with the promotion, then the Bonus Target for such Participant will equal the greater Bonus Target in effect after such promotion and will be measured as a percentage of the Participant's Base Salary.
- If a Participant moves to a position and/or responsibility level with a lower Bonus Target during a performance year, then the Bonus Target for such Participant will equal the lower Bonus Target in effect after such move and will be measured as a percentage of the Participant's Base Salary.

**Weighting of Performance Objectives**

The Bonus Target for the CEO is based solely on Dynavax's achievement of corporate goals ("*Corporate Performance*"). The Bonus Target for each employee other than the CEO is based on Corporate Performance and each Participant's individual performance, including each Participant's contribution to Corporate Performance (collectively, "*Individual Performance*"). Dynavax's Board or Compensation Committee periodically reviews and determines the weighting between these two elements in determining bonuses under the Bonus Plan, with input from Dynavax's management, as set forth in the Annual Criteria. The weighting between Corporate Performance and Individual Performance varies by level within Dynavax.

**Corporate Performance**

After the end of a performance year, Corporate Performance will be assessed by the Board or Compensation Committee, who will determine the "*Corporate Performance Multiplier*" for the performance year, which will reflect this assessment, as well as other successes and considerations the Board or Compensation Committee may deem relevant for the performance year. Unless determined otherwise, Dynavax will apply the same Corporate Performance Multiplier for all Participants for a given performance year. The Board or Compensation Committee may set the Corporate Performance Multiplier above 100%, but in any event not above 175%.

**Individual Performance**

After the end of a performance year, each Participant's Individual Performance will be assessed by the Board, Compensation Committee and/or management, as applicable, who will determine the "*Individual Performance Multiplier*," which will reflect this assessment, as well as other successes and considerations as determined after the end of each performance year by management or, in the case of Executive Officers (other than the CEO), by the Board or Compensation Committee, as set forth in the Annual Criteria. The Board or Compensation Committee will take into account the recommendations and evaluation of each Executive Officer's Individual Performance by the CEO or the Office of the President. A Participant's Individual Performance Multiplier may be above 100% but, in any event, not above 175%.

**Determination and Payment of Bonuses**

The bonus amount paid to each Participant will be determined as follows:

| **Corporate Performance Portion** | | **Individual Performance Portion** | | **Total** |
|---|---|---|---|---|
| Base Salary x Bonus Target x Corporate Performance Multiplier x Weighting | + | Base Salary x Bonus Target x Individual Performance Multiplier x Weighting | = | |

Dynavax maintains absolute discretion in determining the scope and impact of accomplishments as well as the final bonus payout for all Participants. Participants who have received formal disciplinary action during or after a performance year may have their bonus payout reduced or eliminated for that performance year, at the sole discretion of management or the Board or the Compensation Committee, as applicable.

All payments made under this Bonus Plan will be subject to recoupment in accordance with any clawback policy that Dynavax adopts pursuant to the listing standards of any national securities exchange or association on which Dynavax's securities are listed or otherwise, whether before or after the date of any payment made under this Bonus Plan. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with Dynavax or any of Dynavax's affiliates.

Bonuses for a performance year will be paid in cash to each Participant (or his/her beneficiary, in the event of death) by March 15th of the following year, except (i) as is otherwise determined in the sole discretion of the Board, the Compensation Committee or management, as appropriate, or (ii) as may be necessary or advisable to comply with regulations, laws, employment agreements or employment contracts applicable to a particular Participant; *provided*, *however*, that in all cases, the payment date of any bonus for any Participant who is subject to Section 409A of the Internal Revenue Code of 1986, as amended, or any state law of similar effect ("*Section 409A*") will be designed to either comply with Section 409A or satisfy an exemption from application of Section 409A, and the Bonus Plan will be administered and interpreted to the greatest extent possible in compliance with Section 409A or in accordance with such exemption, as applicable. Benefits under this Bonus Plan are not transferable, and the Bonus Plan is unfunded.

**Miscellaneous**

The establishment of this Bonus Plan, any provisions of this Bonus Plan, and/or any action of the Board, Compensation Committee or management with respect to this Bonus Plan, does not confer upon any Participant the right to continued employment with Dynavax. Dynavax reserves the right to dismiss any Participant at will (at any time, with or without prior notice, with or without cause).

All bonus payments made under this Bonus Plan shall be subject to income and employment tax withholding as required by applicable federal, state or local law.

This Bonus Plan and any amendments thereto shall be construed, administered and governed in all respects in accordance with the laws of the State of Delaware (regardless of the law that might otherwise govern under applicable principles of conflict of laws). If any provision of this Bonus Plan shall be determined to be illegal, invalid or unenforceable, such determination shall in no manner affect the legality, validity or enforceability of any other provision hereof.

**Definitions**

"*Annual Criteria*" means the terms and conditions applicable to a specific performance year, as approved by the Board or Compensation Committee. The Annual Criteria will include the Bonus Targets, the weighting between Corporate Performance and Individual Performance for Participants, corporate goals and individual goals, if any, and other terms approved by the Board or Compensation Committee for such performance year as not inconsistent with the Bonus Plan.

"*Base Salary*" means the total amount of base salary or hourly wages actually paid to the Participant during the period of his or her participation in the Bonus Plan for the applicable performance year, rather than the Participant's base salary level or hourly wage rate at any particular point during the applicable performance year (*e.g.*, the Base Salary for an employee whose base salary or hourly wage rate is adjusted during the applicable performance year or for

an employee who is hired during the applicable performance year will be the total amount of base salary or hourly wage rate actually paid to the employee during the period of his or her participation in the Bonus Plan for the applicable performance period). Base Salary includes (a) any amounts paid by Dynavax during periods of absence and/or leave (*e.g.*, PTO or paid leave benefits from the Company) and (b) with respect to non-exempt employees, any overtime payments. Base Salary does not include any expense reimbursements, relocation payments, incentive compensation, commissions, bonuses (including signing bonuses), amounts received as a result of equity awards, short-term or long-term disability benefits from the state or through a third party benefit plan, or shift differential payments, "on call" pay or similar one-time or unusual payments.

"*Board*" means the Board of Directors of Dynavax Technologies Corporation.

"*Compensation Committee*" means the Compensation Committee of the Board.

"*Executive Officers*" means the Company's executive officers as that term is defined in Section 16 of the Securities Exchange Act of 1934, as amended from time to time, and Rule 16a-1 thereunder.

"*Participant*" means an individual who meets the eligibility requirements in the section above entitled, "Eligibility."

*Adopted by the Compensation Committee on November 12, 2019*

**Exhibit 21.1**

**List of Subsidiaries**

Dynavax GmbH

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3ASR Nos. 333-219781 and 333-207966) of Dynavax Technologies Corporation and in the related Prospectuses, and

(2) Registration Statements (Form S-8 Nos. 333-211747, 333-221832, 333-225525, 333-218470, 333-204506, 333-197838, 333-190313, 333-171552 and 333-233247) pertaining to the Amended and Restated 2011 Equity Incentive Plan, the Amended and Restated 2014 Employee Stock Purchase Plan, the 2017 Inducement Award Plan and the 2018 Equity Incentive Plan of Dynavax Technologies Corporation;

of our reports dated March 11, 2020, with respect to the consolidated financial statements of Dynavax Technologies Corporation and the effectiveness of internal control over financial reporting of Dynavax Technologies Corporation included in this Annual Report (Form 10-K) of Dynavax Technologies Corporation for the year ended December 31, 2019.

/s/ Ernst & Young LLP

San Francisco, California
March 11, 2020

**Exhibit 31.1**

**Rule 13a-14(a) Certification of Chief Executive Officer**

CERTIFICATIONS

I, Ryan Spencer, certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ RYAN SPENCER

**Ryan Spencer**
**Chief Executive Officer**
**(Principal Executive Officer)**

Date: March 11, 2020

**Exhibit 31.2**

**Rule 13a-14(a) Certification of Principal Financial Officer**

CERTIFICATIONS

I, Michael Ostrach, certify that:

1. I have reviewed this annual report on Form 10-K of Dynavax Technologies Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ MICHAEL OSTRACH

**Michael Ostrach**
**Chief Financial Officer**
**(Principal Financial Officer)**

Date: March 11, 2020

**Exhibit 32.1**

**Certification Pursuant to Section 1350 of Chapter 63**
**of Title 18 of the United States Code**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Ryan Spencer, Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, to which this Certificate is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set his hand hereto as of the 11th day of March, 2020.

By: /s/ RYAN SPENCER

**Ryan Spencer**
**Chief Executive Officer**
**(Principal Executive Officer)**

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

**Exhibit 32.2**

**Certification Pursuant to Section 1350 of Chapter 63**
**of Title 18 of the United States Code**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Michael Ostrach, Chief Financial Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Annual Report on Form 10-K for the for the fiscal year ended December 31, 2019, to which this Certificate is attached as Exhibit 32.2 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set his hand hereto as of the 11th day of March, 2020.

By: /s/ MICHAEL OSTRACH

**Michael Ostrach**
**Chief Financial Officer**
**(Principal Financial Officer)**

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.