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, 2020

☐ **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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2020 as reported on the Nasdaq Capital Market, was approximately $884.4 million. Shares of common stock held by each officer and director and by each person known to the Company who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 22, 2021, the registrant had outstanding 113,256,101 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2021 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, 2020.

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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 the direct and indirect impact of the ongoing COVID-19 global pandemic on our business and operations, including sales of HEPLISAV-B®, our ability to successfully commercialize HEPLISAV-B, our anticipated market opportunity and level of sales of HEPLISAV-B, our ability to manufacture sufficient supply of HEPLISAV-B to meet future demand, our business, collaboration and regulatory strategy, our ability to successfully support the development and commercialization of other vaccines containing our novel adjuvant CpG 1018, including any potential vaccine for COVID-19, our ability to manufacture sufficient supply of CpG 1018 to meet potential future demand in connection with new vaccines, including any potential COVID-19 vaccine, and to 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 subsidiaries.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found in the more detailed discussion that follows this summary, and the below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described herein as part of your evaluation of an investment in our securities:

- HEPLISAV-B has been launched in the United States, and approved in the European Union, 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.
- Our business and operations have been and may continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic. While we have entered into collaborative relationships to develop vaccines utilizing CpG 1018, including collaborations to develop a vaccine for COVID-19, our collaborators generally have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval, and these collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 are inadequate; we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.
- 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.
- We are subject to ongoing United States Food and Drug Administration ("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.
- 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 limit our marketing claims, we may be unable to generate significant revenues, if any.
- 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 sufficient or any revenues and our business will be harmed.
- 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 or CpG 1018, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance 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.
- 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.
- As a biopharmaceutical company, we engage clinical research organizations ("CROs") to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with good clinical practice 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.
- 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.
- HEPLISAV-B and most of our earlier stage programs, including our CpG 1018 adjuvant rely on oligonucleotide toll-like receptor ("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.

- As we plan for broader commercialization of HEPLISAV-B and for expanded capacity to manufacture CpG 1018, our financial commitments to increase supply capacity might outpace actual demand for our products. Also, if we are unable to maintain our production operations in Dusseldorf and our existing supplier for CpG 1018, we would have to establish alternate qualified manufacturing capabilities, which could result in significant additional operating costs and delays in developing and commercializing HEPLISAV-B and any potential vaccine utilizing CpG 1018. There can be no assurance that we or other third parties will be able to produce CpG 1018 at a cost, quantity and quality sufficient to support our existing or any future collaborations.
- We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture HEPLISAV-B. 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.
- As we continue to grow as a commercial organization and enter into supply agreements with customers, those supply agreements will have obligations to deliver product for which we are reliant upon third parties to manufacture on our behalf.
- HEPLISAV-B is subject to regulatory 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.
- 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.
- 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.
- 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.
- As we focus on commercialization of HEPLISAV-B, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.
- 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.
- 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 face product liability exposure, which, if not covered by insurance, could result in significant financial liability. Our business operations are vulnerable to interruptions by natural disasters, health epidemics and other catastrophic events beyond our control, the occurrence of which could materially harm our manufacturing, distribution, sales, business operations and financial results. Significant disruptions of information technology systems or breaches of data security could also adversely affect our business.
- 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.
- 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.
- 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.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a commercial stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our first marketed 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. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S. 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. We have worldwide commercial rights to HEPLISAV-B and we market it in the United States. We received Marketing Authorization approval of HEPLISAV-B in February 2021 from the European Commission following a positive recommendation in December 2020 from the European Medicines Agency ("EMA") Committee for Medicinal Products ("CHMP") for Human Use for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We expect to launch HEPLISAV-B in the European Union ("EU") in late 2021, initially focusing on one or a few key countries where it would be commercially feasible to market HEPLISAV-B on our own or through third-parties.

We also manufacture and sell CpG 1018, the adjuvant used in HEPLISAV-B. We developed CpG 1018 to provide an increased vaccine immune response, as demonstrated in HEPLISAV-B. We are expanding the use of CpG 1018 to support the development and potential large-scale manufacturing of additional vaccines through collaborations with multiple vaccine companies and academic groups and in our own vaccine development programs. Current collaborations are focused on adjuvanted vaccines for COVID-19, with several in clinical development. In September 2020, we entered into a commercial supply agreement to provide our collaborator Valneva Scotland Limited ("Valneva") with CpG 1018 to produce 60 to 100 million doses of their vaccine in 2021 and up to an additional 90 million doses through 2024. Our tetanus, diphtheria, and acellular pertussis ("Tdap") booster vaccine candidate, adjuvanted with CpG 1018, is in a Phase 1 study and a CpG 1018 based influenza vaccine is expected to enter clinical development during 2021.

COVID-19 Update

We are continuing to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important new vaccines to patients as rapidly as possible.

Our customers' procurement activities coupled with restrictions at healthcare facilities during the pandemic, has negatively affected our sales of HEPLISAV-B. This is consistent with reduced utilization of adult vaccines generally, because focus in healthcare has been acutely placed on the treatment and prevention of COVID-19. The COVID-19 pandemic continued to disrupt the adult vaccine market in the fourth quarter with market utilization shifting back to a sharp decline from the third quarter recovery trend. The total adult hepatitis B market saw a reduction in utilization of approximately 35% in the fourth quarter compared to the same period last year. In the third quarter, utilization was down approximately 24% from the same period last year. Additionally, Centers for Disease Control and Prevention ("CDC") guidance requiring 14-day spacing of vaccines before and after COVID-19 vaccine administration began to stall other adult vaccine utilization in the month of December and has continued to impact utilization into the first quarter which is a trend we believe will continue throughout the first half of 2021. Although utilization of vaccines generally has decreased during the pandemic, our sales efforts have continued to increase our market share.

We have also seen increased interest in our advanced adjuvant, CpG 1018, from our collaborators who are focused on developing COVID-19 vaccines of their own, as well as other potential vaccine candidates targeted at other indications. As a result, we have been working with our supplier to secure additional manufacturing capacity to help support this increased interest in CpG 1018.

Currently, our HEPLISAV-B post-marketing observational studies are fully enrolled and continuing uninterrupted. Due to the design and conduct of the studies, we do not anticipate an impact to the integrity of the studies from "shelter in place" mandates. The HEPLISAV-B dialysis study is able to continue, because the dialysis treatment is classified under "essential travel" exemptions.

The extent of the impact of the COVID-19 pandemic on our ability to generate sales and revenues, our regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance. For additional information on the various current and future potential risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors, included herein.

OUR STRATEGY

Our primary objectives are to make HEPLISAV-B the standard of care in the U.S. for immunization of adults against hepatitis B and to establish CpG 1018 as a premier vaccine adjuvant.

Our strategy for HEPLISAV-B is to focus our commercial efforts on:

- converting the current market to HEPLISAV-B,
- expanding adult immunization and coverage rates,
- increasing second dose compliance, and
- expanding our market to persons with diabetes.

Our strategy for CpG 1018 is to demonstrate its potential to provide a robust immune response in a range of novel vaccines by collaborating with leading commercial and academic vaccine developers throughout the world. We believe that successful development of CpG 1018 adjuvanted vaccines will enable us to become a commercial supplier of adjuvant to our commercial partners and provide a potential source of new vaccines for further advancement by Dynavax. In addition, through collaborations with our partners, we continue to pursue additional vaccine candidates adjuvanted with CpG 1018, including, but not limited to, vaccine candidates for Tdap and universal influenza. We also expect that we could attempt to develop other vaccine candidates for additional indications, either alone or with collaborators, in the future.

HEPLISAV-B

The Company's first commercial product, HEPLISAV-B (Hepatitis B Vaccine, (Recombinant), Adjuvanted), is approved by the FDA and the European Commission (approved in the EU in February 2021) for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

HEPLISAV-B combines CpG 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 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, or through tattooing or the use of razors contaminated with infected blood.

Recommendations for Adult Vaccination to Prevent Hepatitis B

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 persons 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 by HEPLISAV-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 also conducting an open-label, single arm study evaluating a 4-dose regimen of HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis. In January 2021, we reported final immunogenicity results that included a seroprotection rate of 89.3% with high levels of anti-HBs antibodies. Interim safety data showed HEPLISAV-B is well tolerated and no safety concerns were observed. Interim data may not be indicative of any data post-completion of this trial and we cannot guarantee that HEPLISAV-B will be safe or effective, or otherwise successful in this clinical trial. Due to the general health condition of the patient population participating in this particular study, adults with end-stage renal disease undergoing hemodialysis, we do expect to see a higher potential incidence of adverse events reporting than what we saw with previous trials for HEPLISAV-B. We expect that the last patient visit for this trial will be in September 2021, and we expect full safety data by the end of 2021. The safety and effectiveness of HEPLISAV-B in adults on hemodialysis have not yet been established. This study alone, regardless of results, may not be sufficient to support a label change to include dialysis.

Commercialization of HEPLISAV-B

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"). HEPLISAV-B is currently approved in the U.S. and the EU for the prevention of hepatitis B. We are also exploring additional territories where it would be commercially feasible to market HEPLISAV-B on our own or through third parties.

Based on 2019 data, we estimate that the current total U.S. market opportunity for HEPLISAV-B net sales is approximately $400 million annually, excluding what we believe are temporary COVID-related reductions in utilization of adult vaccines generally. We also believe that the market opportunity could increase to over $600 million annually when allowing for expanding adult immunization and coverage rates, increased second dose compliance, price increases over time 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 65 people across 3 regions.

We are currently studying a four-dose regimen of HEPLISAV-B for patients on hemodialysis. If we receive approval 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 70%.

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, in 2018, 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.

The ACIP also is considering adoption of policy initiatives aimed at a universal adult recommendation and preferential use for HEPLISAV-B. Additional sources of potential growth in the market opportunity for HEPLISAV-B include improved second dose compliance and increases in adult immunization and coverage rates.

VACCINES AND VACCINE ADJUVANTS

Vaccines 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 induce 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 CpG 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 in 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.

CPG 1018

The favorable immunogenicity and safety results achieved with CpG 1018 adjuvanted HEPLISAV-B support our efforts to develop CpG 1018 as a broadly useful vaccine adjuvant platform. CpG 1018 has an established profile for the potential development of safe and effective vaccines. CpG 1018 has a well-defined mechanism of action, targeting select immune system cells, with well-characterized effects on the immune response that mimic the immune response to naturally occurring TLR9 agonists in pathogens, resulting in potent adjuvant activity for antibody responses. In HEPLISAV-B, CpG 1018 drives faster and consistently higher rates of seroprotection including in the elderly and populations known to be less responsive to other vaccines. CpG 1018 differentially elicits a preferred T Helper 1 ("Th1") cell polarized response, driving both production of antibodies and T-cell activation. CpG 1018 has a large safety database indicating a favorable reactogenicity profile with lower reactogenicity compared to other adjuvants.

We have established several clinical and preclinical collaborations with vaccine developers to evaluate CpG 1018 adjuvanted vaccine product candidates against COVID-19, flu and other infectious diseases. Data from studies in non-human primates demonstrate CpG 1018 can elicit a robust immune response to COVID-19 and protect animals from infection in challenge studies. Initial results from Phase 1 human clinical studies demonstrated a CpG 1018 adjuvanted vaccine induced strong immune responses, including neutralizing antibodies and cell-mediated immunity and demonstrated a favorable safety and tolerability profile.

Valneva Supply Agreement

In April 2020, we entered into a collaboration agreement with Valneva to provide CpG 1018 adjuvant for use in the development of Valneva's COVID-19 vaccine candidate, and in September 2020, we entered into a supply agreement with Valneva to manufacture and supply CpG 1018 adjuvant for use in the commercialization of Valneva's COVID-19 vaccine candidate. Under the supply agreement we will provide Valneva with CpG 1018 to produce 60 to 100 million doses of vaccine in 2021 and up to an additional 90 million doses through 2024 to support Valneva's contract with the U.K. government. Phase 1/2 clinical trials of the Valneva vaccine candidate were initiated in December 2020.

Serum Institute of India

In June 2017, we entered into an agreement with Serum Institute of India Pvt. Ltd. ("SIIPL") to collaborate on development and commercialization of certain potential vaccines. Our initial program is the development of an improved Tdap booster vaccine candidate adjuvanted with CpG 1018. A Phase 1 clinical trial began inJanuary 2021. Under the collaboration, Dynavax has exclusive worldwide rights to commercialize the vaccine, and SIIPL has exclusive rights to distribute in India and to fulfill WHO/UNICEF tender contracts. Each party is responsible for clinical development cost in their respective territories.

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. B-Class TLR9 agonists, such as our CpG 1018 vaccine adjuvant, stimulate release of cytokines necessary for T cell activation and establishing long-term immunity. TLR9 stimulation also helps generate memory 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.

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, 2020, our intellectual property portfolio included over 25 issued U.S. patents, over 80 issued or granted foreign patents and over 25 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. Some of these patents and patent applications relate to our discontinued immuno-oncology programs. Reductions in counts, relative to prior years, are reflective of the assets we sold during 2020 following such discontinuation and other decisions we took consistent with our focus on our vaccine business. 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 20 years from the earliest effective filing date.

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 2041.

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 file for protection of the inventions set forth in these patent applications or in our issued patents. Further, there could be proceedings such as inter partes review (IPR), post grant review (PGR), reexamination, or reissue which could result in claims in our patents being narrowed or even invalidated.

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 by 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.

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. Litigation or any other proceedings 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 compete with several commercially available vaccine and adjuvant products. Many companies and institutions are making substantial investments in developing additional vaccines and adjuvants that could compete directly or indirectly with our marketed products and products under development by us and our collaborators.

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 EU and the 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 manufactured by VBI Vaccines Inc. ("VBI") is approved in Israel, and recently completed Phase 3 trials in the United States, Europe and Canada. While we believe that HEPLISAV-B competes very well with other approved vaccines available on the market, we are still a relatively new entrant and we face significant competition in our longer term goal to capture 60-70% of the U.S. market share. While we may explore additional territories outside of the U.S. and the EU to market HEPLISAV-B, in doing so we will likely face competition from these or other products and competitors.

We are also in competition with companies developing vaccines, and vaccine adjuvants, generally, including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Seqirus, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson 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 ("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 ("cGMP") regulations for pharmaceuticals; 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, or those of our collaborators, 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 ("GCP") 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 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 False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or to have offered improper inducements to federal health care program beneficiaries to select a particular provider or supplier. The federal Anti-Kickback Statute is broad, and despite a series of narrow statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. In addition, where such activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our activities with physician customers, pharmacies, and patients, as well as our activities pursuant to partnerships with other companies and pursuant to contracts with contract research organizations, could be subject to challenge under one or more of such laws.

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

Privacy and Security Laws. We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and, in the EU and the European Economic Area, or EEA, the GDPR (Regulation 2016/679). New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened.

Effective May 25, 2018, the EU implemented the General Data Protection Regulation ("GDPR") a broad data protection framework that expands the scope of current EU data protection law to non-EU entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data. The GDPR implements more stringent operational requirements than its predecessor legislation.

Further, the Court of Justice of the EU ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the EU and United States, was invalid and could no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses ("SCCs"), while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield.

Additionally, Brexit took effect in January 2020, which will lead to further legislative and regulatory changes. While the Data Protection Act of 2018, that "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful in the long term under GDPR. With the expiry of the transition period on December 31, 2020, companies will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which has the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. We may incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

Also, in June 2018, the State of California enacted 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.

Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA.

"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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and other healthcare professionals and teaching hospitals and ownership or investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. 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.

Penalties. 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 signed several 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 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 (the "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 eliminated 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." 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. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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.

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. As is common in our industry in light of FDA inspection and licensing requirements for manufacturing sites, we have relied on a limited number of suppliers to produce products for clinical trials, conduct fill/finish operations, and a single supplier to produce our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators. Switching suppliers, or bringing on additional suppliers, could be complicated and time consuming, but we generally seek to maintain inventory to help bridge any unexpected gap in supply. In order to help us successfully manufacture and commercialize HEPLISAV-B, we have secured long-term supply agreements with the key third-party suppliers and vendors for commercial supply of our component products and finished goods. 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 our website 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, we offer incentives to our 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 have a policy to allow our employees to telecommute one or more days a week when our offices are not closed as a COVID-19 precautions, in which case our workforce is permitted be almost fully remote, 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.

Human Capital Resources

As of December 31, 2020, we had 245 employees, comprised of 142 employees in the U.S., including 82 employees at our corporate headquarters in Emeryville, California and 60 field-based employees located throughout the U.S., as well as 103 employees in our office and manufacturing facility in Düsseldorf, Germany. Many of our employees hold advanced degrees, including masters degrees and Pharm.D., Ph.D. or M.D. degrees. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future prospects. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be very good.

Retention

Historically, our annual turnover has typically been lower than the turnover in our industry. Our total turnover rate for 2020 was 12.5% in the U.S. and less than 7% in Düsseldorf. As a vaccine-focused company, we face stiff competition to hire and retain our employees which is exacerbated by the current and intense global focus to develop and distribute a COVID-19 vaccine, as market participants in the COVID-19 space grow their businesses and seek to do so by hiring professionals with vaccine experience in particular. The average tenure among our employees, is 5.6 years in Düsseldorf and 3.1 years in the U.S.

Development

Attracting and retaining top talent is key to the achievement of our strategic goals. The development and engagement of our employees is also a top priority of the human resources team, and in 2020, eighty of our global leaders and key contributors completed a seven-module leadership development program. In 2020, we implemented a new online recognition program in the U.S. and will expand the program to Düsseldorf in April 2021.

Response to COVID-19

In response to the pandemic, we moved to a virtual working model in the U.S. and through work-from-home and creative scheduling efforts, we reduced the number of employees required to be onsite each day in our Düsseldorf manufacturing facility by approximately 50%. Our last employee survey in October 2020 revealed that 97.3% of U.S. based employees felt that their level of engagement was the same or higher than it was in February 2020, prior to the pandemic.

Compensation

We also monitor our compensation programs closely and provide what we consider to be a very competitive mix of compensation and insurance benefits for all our employees. Each of our employees participates in our equity programs.

CORPORATE INFORMATION & AVAILABLE INFORMATION

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 ("SEC"). Alternatively, you may access these reports at the SEC's website at www.sec.gov. The contents of our websites are not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

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 approved in the European Union, 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.

We are continuing to closely monitor the impact of the COVID-19 global pandemic on our business and are taking proactive efforts to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important new vaccines to patients as rapidly as possible. We have implemented measures to protect the health and safety of our workforce, including a mandatory work-from-home policy for employees who can perform their jobs offsite. In the conduct of our business activities, we are also taking actions to protect the safety of patients and healthcare professionals. Our field-based personnel have mostly paused in-person customer interactions in healthcare settings and are generally using electronic communication, such as emails, phone calls and video conferences. Many health care and contracting professionals at hospitals and other medical institutions with whom our field-based personnel interact are working a greater proportion of their working schedule from home and are facing additional demands on their time during the COVID-19 pandemic. We expect that the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, may reduce the effectiveness of our sales personnel, our customers' procurement activities, as well as those of our collaborators, which could negatively affect our product sales.

In addition, due to the ongoing COVID-19 global pandemic, most medical centers restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in mid-March 2020. As states began phasing out restrictions in late May/early June, medical centers began operating under limited capacity and strict social distancing rules. This has resulted in significantly reduced utilization of adult vaccines since the end of the first quarter of 2020, including HEPLISAV-B. This reduced utilization has significantly impacted sales and is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions.

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.

Our business and operations have been and may continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business has been and may continue to be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization ("WHO") as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease. In response to these public health directives and orders, we have implemented work-from-home policies for all employees, except those that need to be at work in order to perform critical responsibilities.

The COVID-19 pandemic, and government measures taken in response, have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business-related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended. In accordance with guidance issued by the Centers for Disease Control and Prevention, WHO and local authorities, beginning in March 2020, most of our global workforce transitioned to working remotely. The principal purchasers of HEPLISAV-B, including independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Departments of Defense and Veterans Affairs and retail pharmacies, have all drastically curtailed their day-to-day activities and ceased or significantly reduced allowing access to their facilities for non-COVID-19 related business. Thus, our field sales and medical science employees increased their use of telephone and web-based means to seek to carry out their roles where necessary, which may not be as effective as being in-person.

The overall impact has generally resulted in significantly reduced utilization of all adult vaccines, (other than recently approved COVID-19 vaccines) since the end of the first quarter of 2020, including HEPLISAV-B. This shift has significantly and adversely impacted our sales of HEPLISAV-B and our business and operating results since March 2020 and continues to pose a headwind for our HEPLISAV-B business. This reduced HEPLISAV-B utilization is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions.

We also cannot predict to what extent the COVID-19 pandemic may continue to disrupt demand for HEPLISAV-B, but the overall magnitude of the disruption to our business will depend, in part, on the length and ongoing severity of the restrictions, and other limitations on our ability to conduct our business in the ordinary course. Prolonged disruptions would likely materially and negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders related to COVID-19 have had no material impact on the supply of HEPLISAV-B and we have no current expectation that they will. However, if such restrictions continue for a substantial period of time, they could impact personnel at our manufacturing facility in Germany and third-party manufacturing facilities in the United States. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B sufficient to meet demand.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact, and the duration of such impact, brought by COVID-19 may be difficult to assess or predict, a widespread pandemic could also potentially result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve, and new variants of the virus have been discovered. While some vaccines have been recently approved, it is not clear whether, which, or to what extent these vaccines will protect against current or future variants of the virus. The extent to which the COVID-19 pandemic impacts our business, our future sales of HEPLISAV-B and revenue will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, social distancing requirements and business closures in the United States and elsewhere, business disruptions and the effectiveness of actions taken in the United States and elsewhere to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, operations or the global economy as a whole. However, these impacts could continue to adversely impact our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

As we continue to focus on the commercialization of HEPLISAV-B and CpG 1018, 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 CpG 1018, 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, or secure sufficient or timely supply from third party service providers, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

As we plan for broader commercialization of HEPLISAV-B and for expanded capacity to manufacture CpG 1018, our financial commitments to increase supply capacity might outpace actual demand for our products.

As we plan to scale up production capabilities for HEPLISAV-B as well as production capabilities for our advanced adjuvant, CpG 1018, to support potential vaccine collaborations and response to COVID-19 and other initiatives, we have been, and in the future will be, required to make significant financial commitments to reserve manufacturing capacity at our contract manufacturing organizations (“CMOs”). Under ordinary circumstances we would make these commitments close in time and with some level of certainty that we have customers making similar commitments to us. Because of long lead times on manufacturing, uncertainty about who will ultimately buy CpG 1018 from us and in what quantities, if any, as well as the need to book manufacturing capacity in advance, the financial commitments we make to our CMOs to support manufacturing may not be recovered in its entirety, or at all, if our collaborators do not ultimately purchase from us. Capacity reservation fees are generally not recoverable if we do not use the capacity we have reserved as a result of lower than expected demand, or otherwise. As a result, we could end up making financial commitments that we never recover if demand for CpG 1018 does not materialize in the volumes we are expecting, or at all.

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 surface 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 rely on a contract manufacturer to do so. Our contract manufacturer is the only approved provider that we have, and there can be no assurance that we or they 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 CpG 1018 for HEPLISAV-B and our pre-filled syringe presentation. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing supplier for CpG 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in manufacturing HEPLISAV-B and developing and commercializing our product candidates. 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.

We have entered into collaborative relationships to develop vaccines utilizing CpG 1018, including collaborations to develop a vaccine for COVID-19. These collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 are inadequate; we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.

As part of our business, we are working to develop our novel adjuvant, CpG 1018, as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. There are risks and uncertainties inherent in vaccine research and development, including the timing of completing vaccine development, the results of clinical trials, whether the vaccine will be approved for use, the extent of competition, and whether a vaccine can be successfully commercialized. As a result, these collaborative efforts may not be as successful as we expect, or at all.

In addition, our collaborators have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval of potential vaccines, including any potential vaccine for COVID-19 containing CpG 1018. We have limited or no control over our collaborators' decisions, including the amount and timing of resources that any of these collaborators will dedicate to such activities. If a collaborative partner fails to conduct collaborative activities successfully, the development of a vaccine could be delayed, and may not occur at all. We also rely on a single supplier to produce CpG 1018. If we were unable to maintain our existing supplier for CpG 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 any potential adjuvanted vaccines by our third-party collaborators. We or other third parties may not be able to produce CpG 1018 at a cost, quantity and quality similar to that available from our current third-party supplier, or at all, and even if we add an additional supplier, there is no guarantee such supplier will be able to manufacture supplemental quantities sufficient to support commercial demand to the extent it materializes and in the timeframes required.

CpG 1018 has no composition of matter patent protection. We have filed patent applications claiming compositions and methods of use of CpG 1018 for COVID-19 and other vaccines. In addition, we rely on trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to CpG 1018. If we are unable to adequately obtain or enforce our proprietary rights relating to CpG 1018, we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), including those over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

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 we believe 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.

We have applied for, and in some cases have received, grants to help fund the scale-up of CpG 1018 production, and such grants, if and when received, may involve pricing or other restrictions.

In order to help fund potential scale-up of production of CpG 1018 that may be required in the event that CpG 1018 is included in any approved and commercially-available novel vaccine, whether a COVID-19 vaccine or otherwise, we have applied for, and in some cases have received grants from various charitable and philanthropic organizations, including from Bill and Melinda Gates Foundation. These grants and others, if and when received, may come with certain pricing requirements, global access requirements or reporting or other covenants to ensure that any funded product is made available by us worldwide and on a nondiscriminatory basis. Such covenants may limit the price we can charge for any funded product and may involve a license to use technology we own that is included in the funded products if we do not comply. Such price limitations or licenses, if invoked, could serve to limit the prices we charge, or in some cases, our control over the manufacturing and distribution of grant-funded products. Failure to agree with such requirements, may result in the company not receiving some or all of the grant.

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 CpG 1018 adjuvant. We recently announced the sale of assets related to our SD-101 program. Additionally, we are seeking strategic alternatives for of the remaining assets in our immuno-oncology portfolio, including our development stage product 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 the assets that remain in 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 assets 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 assets 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 concluded in November 2020. We must also 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 the 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 would 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 current good manufacturing practices (“cGMP”), good clinical practices (“GCP”), ICH guidelines, and good laboratory practices (“GLP”). If we are not able to meet and maintain regulatory compliance, we may lose marketing approval and be required to withdraw our product. Withdrawal of our product 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 U.S. and European approvals of HEPLISAV-B 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 sufficient or any revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing vaccines and adjuvants. 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 United States. 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 manufactured by VBI Vaccines Inc. ("VBI") is approved in Israel, and recently completed Phase 3 trials in the United States, Europe and Canada.

We are also in competition with companies developing vaccines and vaccine adjuvants, generally, including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Seqirus, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson 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 CpG 1018, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We have generated limited revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net losses for the year ended December 31, 2020 and 2019 were $75.2 million and $152.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of $1.3 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. While new sales of CpG 1018 may generate revenue during the pandemic, there is no guarantee that such revenues will be sustainable in the long term. The timing for uptake of our products in the U.S. has further increased losses related to commercialization. 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 or that if we are able to reach profitability that it will be sustainable for any period of time.

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, 2020, we had $165.0 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 and development and commercialization of our CpG 1018 adjuvant. 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 or equity financings. 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.

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. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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.

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.

We may continue to 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, to various additional 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 and 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.

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

HEPLISAV-B 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, 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.

As we continue to grow as a commercial organization and enter into supply agreements with customers, those supply agreements will have obligations to deliver product that we are reliant upon third parties to manufacture on our behalf.

As our commercial business begins to expand in connection with commercial sales of HEPLISAV-B and CpG 1018, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain quantities and meeting certain quality thresholds, among other things, all within specified timeframes. If, for any reason, whether due to reliance on third-party manufacturers or otherwise, we are unable to deliver timely, compliant products to our customers in quantities that meet our contractual obligation, we could be subject to lost revenue, contractual penalties, suits for damages, harm to our reputation or other problems that could materially and adversely affect our business.

HEPLISAV-B is subject to regulatory 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.

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 to 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 $180.9 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 otherwise 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 are (i) $30 million for the period July 1, 2019 through June 30, 2020, (ii) $50 million for the period July 1, 2020 through June 30, 2021, (iii) $75 million for the period July 1, 2021 through June 30, 2022 and (iv) $100 million for the period July 1, 2022 through June 30, 2023. In November 2020, we entered into an amendment to the term loan agreement that, among other things, (i) changes the annual revenue requirement to include all revenue, including CpG 1018 net sales, rather than net sales of HEPLISAV-B only, and (ii) deletes the $50 million revenue requirement for the period from July 1, 2020 through June 30, 2021 in its entirety. 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.

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 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- 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 on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors 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 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.

It remains unclear how various state, federal, and international privacy and cybersecurity law will affect our business. For example, we don't know 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.

Internationally, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition. Also, mechanisms for legally transferring information under the GDPR remain unclear. At present, there are few if any viable alternatives to the SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

In addition, our data security and information technology systems, as well as those of our partners and contractors, are potentially vulnerable to data security breaches, whether by employees or others, that may expose sensitive data or personal information to unauthorized persons.

Enacted or future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may have an adverse effect on our operations and business.

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 signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress 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 eliminated 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". 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. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures will impact the ACA and our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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.

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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments

for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business. However, 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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.

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 products, 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 administrative proceedings related to our intellectual property which causes us to incur certain legal expenses. If we become involved in any litigation and/or other significant 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 or other 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 products or product candidates will decrease, and we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.

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, or other disclosures which impact patentability, 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.

For example, CpG 1018 has no composition of matter patent protection in the United States or elsewhere. We must therefore rely primarily on the protection afforded by method of use patents relating to the use of CpG 1018 in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to CpG 1018. We have filed patent applications claiming compositions and methods of use of CpG 1018 for COVID-19 and other vaccines, but we cannot provide any assurances that we will receive an issued patent for any of these patent applications or that, if issued, any of these patents will provide adequate protection for any intended use of CpG 1018 in vaccines. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018, we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018.

The biopharmaceutical patent environment outside the U.S. is also uncertain. We may be particularly affected by this uncertainty since several of our product candidates or our collaborators' vaccine candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection, if any. For example, while many countries such as the United States permit method of use patents relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving and may be unfavorably interpreted to prevent us from successfully prosecuting some or all of our pending patent applications relating to the use of CpG 1018. There are some countries that currently do not allow such method of use patents, or that significantly limit the types of uses that are patentable.

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 now or in the future;
- 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;
- pending patent applications or issued patents may be challenged by third parties in proceedings, such as inter partes review ("IPR"), pre- and post-grant oppositions, and post grant review ("PGR").

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:

- impact of COVID-19 on our HEPLISAV-B product revenue;
- 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;
- 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 products or 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.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies, including recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models or prospects of those companies. These broad market fluctuations have adversely affected and may in the future adversely affect the market price of our common stock. In this regard, worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic may negatively affect the market price of our common stock, regardless of our actual operating performance.

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.

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 sales agreement with Cowen, under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million.

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.

General Risk Factors

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.

Our business operations are vulnerable to interruptions by natural disasters, health 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 the ongoing COVID-19 pandemic, or the fear of such events, could cause restrictions on supply chains, access to workplaces and affect employee health and availability.

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, California, 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 adversely affect our business and operations.

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. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely. 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 data 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 GDPR, resulting in significant penalties; increased costs; loss of revenue; expenses of computer or forensic investigations; material fines and penalties; compensatory, special, punitive or statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; or injunctive relief. News reports have also highlighted COVID research-specific hacking and phishing attempts. Because we and our collaborators are working on vaccines, including potential COVID vaccines, we may be at higher-than-average risk for such attempts.

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.

U.S. and international authorities have been warning businesses of increased cybersecurity threats from actors seeking to exploit the COVID-19 pandemic. We have recently experienced a cybersecurity incident known as a phishing e-mail scam, and although we do not consider its impact on us to be material, if we are unable to prevent this or other 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. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2020, 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.

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".

As of February 22, 2021, 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. Additionally, in February 2018, we entered into a $175.0 million term loan agreement with CRG Servicing LLC, which 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 Company has elected to comply with Item 301 of Regulation S-K, as amended February 10, 2021 and is omitting this disclosure in reliance thereon.

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 the Consolidated Financial Statements and the related notes thereto set forth in "Item 8—Financial Statements and Supplementary Data."

Overview

We are a commercial stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our first marketed 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 also manufacture and sell CpG 1018, the adjuvant used in HEPLISAV-B. We are working to develop CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza.

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 and we market it in the United States. 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. In addition, we received Marketing Authorization approval of HEPLISAV-B in February 2021 from the European Commission following a positive recommendation in December 2020 from the European Medicines Agency ("EMA") Committee for Medicinal Products ("CHMP") for Human Use for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We expect to launch HEPLISAV-B in the European Union in late 2021, initially focusing on one or a few key countries where it would be commercially feasible to market HEPLISAV-B on our own or through third-parties.

All of our HEPLISAV-B sales are 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, 2020, HEPLISAV-B product revenue, net was $36.0 million.

In the third quarter of 2020, we commenced selling our novel adjuvant, CpG 1018, to certain of our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. For the year ended December 31, 2020, CpG 1018 product revenue, net was $3.3 million. In the third quarter of 2020, we also announced a commercial supply agreement with Valneva Scotland Limited ("Valneva") to cover the supply of CpG 1018 for up to 190 million doses of their SARS-COV-2 vaccine candidate, subject to the terms of the agreement and contingencies contained therein.

In May 2020, we completed an underwritten public offering of 16,100,000 shares of our common stock at a public offering price of $5.00 per share. The net proceeds from this offering were approximately $75.4 million, after deducting the underwriting discount and other offering expenses.

In August 2020, we entered into a new At Market Sales Agreement with Cowen ("2020 ATM Agreement"), which replaced the 2017 At Market Sales Agreement ("2017 ATM Agreement"). Under the 2020 ATM Agreement, we can offer and sell up to $150 million of our common stock from time to time. For the year ended December 31, 2020, we received net cash proceeds of $33.1 million from sales of 8,114,643 shares of our common stock under the 2017 ATM Agreement and 2020 ATM Agreement.

In July 2020, we sold assets related to our immuno-oncology compound, SD-101, to Surefire Medical Inc. d/b/a TriSalus Life Sciences ("TriSalus"). Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction and $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound. In the third quarter of 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, net of transaction costs.

COVID-19 Update

We are continuing to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important new vaccines to patients as rapidly as possible.

Our customers' procurement activities coupled with restrictions at healthcare facilities during the pandemic, has negatively affected our sales of HEPLISAV-B. This is consistent with reduced utilization of adult vaccines generally, because focus in healthcare has been acutely placed on the treatment and prevention of COVID-19. The COVID-19 pandemic continued to disrupt the adult vaccine market in the fourth quarter with market utilization shifting back to a sharp decline from the third quarter recovery trend. The total adult hepatitis B market saw a reduction in utilization of approximately 35% in the fourth quarter compared to the same period last year. In the third quarter, utilization was down approximately 24% from the same period last year. Additionally, Centers for Disease Control and Prevention ("CDC") guidance requiring 14-day spacing of vaccines before and after COVID-19 vaccine administration began to stall other adult vaccine utilization in the month of December and has continued to impact utilization into the first quarter which is a trend we believe will continue throughout the first half of 2021. Although utilization of vaccines generally has decreased during the pandemic, our sales efforts have continued to increase our market share.

We have also seen increased interest in our advanced adjuvant, CpG 1018, from our collaborators who are focused on developing COVID-19 vaccines of their own, as well as other potential vaccine candidates targeted at other indications. As a result, we have been working with our supplier to secure additional manufacturing capacity to help support this increased interest in CpG 1018.

Currently, our HEPLISAV-B post-marketing observational studies are fully enrolled and continuing uninterrupted. Due to the design and conduct of the studies, we do not anticipate an impact to the integrity of the studies from "shelter in place" mandates. The HEPLISAV-B dialysis study is able to continue, because the dialysis treatment is classified under "essential travel" exemptions.

The extent of the impact of the COVID-19 pandemic on our ability to generate sales and revenues, our regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance. For additional information on the various current and future potential risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors, included herein.

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 in this Annual Report on Form 10-K, 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 – HEPLISAV-B

We sell HEPLISAV-B 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 significant 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. We evaluate our estimates of variable considerations including, but not limited to, product returns, chargebacks and rebates, periodically or when there is an event or change in circumstances that may indicate that our estimates may change. During the fourth quarter of 2020, based on an analysis of historical product returns and customer ordering patterns, we decreased our returns reserve resulting in an increase in HEPLISAV-B product revenue, net of approximately $0.8 million. There were 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.

Product Revenue, Net – CpG 1018

We also sell our novel adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. We have determined that our collaboration partners meet the definition of customers under ASC 606. Therefore, we accounted for our CpG 1018 sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer. Because the timing between the recognition of revenue for product sales and the receipt of payment is less than one year, there is no significant financing component on the related receivables.

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 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.

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. Collaboration and manufacturing service revenue are recorded in other revenue in the 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 ("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. For the year ended December 31, 2020 and 2019, there were no inventory reserves recognized. During 2018, we recorded $1.0 million in inventory reserves, which is included in cost of sales – product.

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, 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

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.

The operating lease right-of-use assets also include any lease payments made and exclude any lease incentives. 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. We have also elected the practical expedient to not separate lease components from non-lease components.

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. Rent revenue 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.

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. For public business entities, excluding smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2019. Furthermore, the one-time determination of whether an entity is eligible to be a smaller reporting company shall be based on an entity's most recent determination as of November 15, 2019, in accordance with SEC regulations. Because we were a smaller reporting company based on the most recent determination as of November 15, 2019, this ASU and its subsequent updates, will be 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 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 adopted this ASU on January 1, 2021 and the adoption of this standard did not have a material impact on our consolidated financial statements.

Accounting Standards Update 2020-06

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2021 with early adoption permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

Results of Operations

Revenues

Revenues consist of amounts earned from product sales and other revenues. Product revenue, net, includes sales of HEPLISAV-B and CpG 1018 adjuvant.

Revenue from HEPLISAV-B product sales is recorded at the net sales price, which includes estimates of product returns, chargebacks, discounts, rebates and other fees. We sell our novel adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. 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 2019 to 2020		Increase (Decrease) from 2018 to 2019	
Revenues:	**2020**	**2019**	**2018**	**$**	**%**	**$**	**%**
HEPLISAV-B	$ 36,030	$ 34,644	$ 6,812	$ 1,386	4%	$ 27,832	409%
CpG 1018	3,277	-	-	3,277	NM	-	NM
Total product revenue, net	$ 39,307	$ 34,644	$ 6,812	$ 4,663	13%	$ 27,832	409%
Other revenue	7,244	575	1,386	6,669	1160%	(811)	(59)%
Total revenues	$ 46,551	$ 35,219	$ 8,198	$ 11,332	32%	$ 27,021	330%

NM = Not meaningful

2020 versus 2019

HEPLISAV-B revenue for the year ended December 31, 2020 increased primarily due to an increase in sales volume. Due to the ongoing COVID-19 global pandemic, most medical centers restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in mid-March 2020, which significantly lowered our sales volume in the second quarter. Utilization of adult vaccines, including HEPLISAV-B, improved in the second half of the year as health care providers gradually expanded their services under strict social distancing rules and our distributors replenished their inventory. Sales fluctuations during the second half of 2020 also included initial stocking orders from a large retail chain and another customer and the effect of seasonal Department of Defense purchases. During the fourth quarter of 2020, based on an analysis of historical product returns and customer ordering patterns, we decreased our returns reserve resulting in an increase in HEPLISAV-B product revenue, net of approximately $0.8 million.

Overall, vaccine utilization is expected to decline significantly in the first quarter of 2021 from the fourth quarter of 2020 to approximately 50% of pre-pandemic levels, which will result in a decrease in HEPLISAV-B revenues in the first quarter of 2021 compared to the fourth quarter of 2020. Utilization of adult vaccines will continue to be impacted throughout the first half of 2021 but is expected to return to pre-pandemic levels in the second half of 2021.

In the third quarter of 2020, we began selling our novel adjuvant, CpG 1018, to our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines.

In September 2020, we received $6.3 million from the Coalition for Epidemic Preparedness Innovations (“CEPI”) to scale up our CpG 1018 production and to make available certain quantities of CpG 1018 for purchases to CEPI and its partners. In October 2020, CEPI terminated the agreement and we recognized the $6.3 million in other revenue.

Other revenue also included collaboration revenue related to services performed under a collaboration agreement with Serum Institute of India Pvt. Ltd. and manufacturing service revenue.

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.

Included in other revenue was collaboration revenue related to services performed in 2019 under a collaboration agreement with Serum Institute of India Pvt. Ltd. Other revenue also included manufacturing service revenue of $0.4 million.

Cost of Sales – Product

Cost of sales - product consists primarily of raw materials, certain fill, finish and overhead costs and any inventory adjustment charges for pre-filled syringes ("PFS") of HEPLISAV-B and inventory costs to produce CpG 1018 for our collaboration partners. Our HEPLISAV-B PFS finished goods inventory previously included components for which a portion of the manufacturing costs were expensed to research and development prior to the approval of the PFS presentation by the FDA in March 2018. Substantially all the inventory that was previously expensed to research and development has been sold to customers. The following is a summary of our cost of sales - product (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2019 to 2020		Increase (Decrease) from 2018 to 2019	
	2020	2019	2018	$	%	$	%
Cost of sales - product	$ 11,410	$ 10,172	$ 10,934	$ 1,238	12%	$ (762)	(7)%

2020 versus 2019

For the year ended December 31, 2020, cost of sales-product increased, as compared to the same period in 2019, primarily due to higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing. Cost of sales – product for the year ended December 31, 2020 also includes $1.4 million of costs to produce CpG 1018 for our collaboration partners. The increase was offset by lower overhead costs and a charge in the third quarter of 2019 related to a terminated batch.

We expect our cost of sales - product for HEPLISAV-B, as a percentage of product sales, net, to stabilize for the foreseeable future, excluding potential unknown one-time charges. We expect our cost of sales-product for CpG 1018 to increase substantially in 2021 due to increased production of CpG 1018 for Valneva and other collaborators.

2019 versus 2018

Cost of sales - product for the year ended December 31, 2019 primarily included 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.

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 2019 to 2020		Increase (Decrease) from 2018 to 2019	
	2020	2019	2018	$	%	$	%
Cost of sales - amortization of intangible assets	$ 2,500	$ 9,217	$ 10,862	$ (6,717)	(73)%	$ (1,645)	(15)%

2020 versus 2019

Cost of sales - amortization of intangible assets consisted of amortization of the intangible asset recorded as a result of sublicense payments to Merck, Sharpe & Dohme Corp. ("Merck"), upon FDA approval of HEPLISAV-B in November 2017. The intangible asset was fully amortized as of April 2020 when the sublicense agreement expired.

2019 versus 2018

Cost of sales - amortization of intangible assets consisted of amortization of the intangible asset recorded as a result of a regulatory milestone and sublicense fees to Coley Pharmaceutical Group, Inc. ("Coley"), Merck and GlaxoSmithKline Biologicals SA ("GSK"), upon FDA approval of HEPLISAV-B in November 2017. The intangible assets related to Coley and GSK were fully amortized in 2018.

Research and Development

Research and development expense consists, primarily, of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services consist of costs associated with clinical development, 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.

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

	Year Ended December 31,			Increase (Decrease) from 2019 to 2020		Increase (Decrease) from 2018 to 2019	
Research and Development:	**2020**	**2019**	**2018**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 10,328	$ 21,933	$ 30,466	$ (11,605)	(53)%	$ (8,533)	(28)%
Outside services	16,064	25,437	28,213	$ (9,373)	(37)%	(2,776)	(10)%
Facility costs	1,215	6,903	6,668	$ (5,688)	(82)%	235	4%
Non-cash stock-based compensation	1,000	8,058	9,604	$ (7,058)	(88)%	(1,546)	(16)%
Total research and development	$ 28,607	$ 62,331	$ 74,951	$ (33,724)	(54)%	$ (12,620)	(17)%

2020 versus 2019

Compensation and related personnel costs and non-cash stock-based compensation decreased due to lower research and development headcount as a result of our restructuring in May 2019. In addition, non-cash stock-based compensation included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020.

The decrease in outside services was primarily the result of winding down of our immuno-oncology programs, partially offset by an increase in outside services due to CpG 1018 development costs at our third-party manufacturing facility to support increased CpG 1018 demand from our collaboration partners for use in their development and/or commercialization of their COVID-19 vaccine candidates.

Facility costs, which are primarily comprised of occupancy and related expenses, decreased due to lower overhead allocation to research and development functions. In addition, facility costs for year ended December 31, 2019 included accelerated depreciation in connection with the restructuring in May 2019.

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 as compared to 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.

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):

	Year Ended December 31,			Increase (Decrease) from 2019 to 2020		Increase (Decrease) from 2018 to 2019	
Selling, General and Administrative:	**2020**	**2019**	**2018**	**$**	**%**	**$**	**%**
Compensation and related personnel costs	$ 31,191	$ 28,525	$ 15,993	$ 2,666	9%	$ 12,532	78%
Outside services	24,759	26,269	31,758	(1,510)	(6)%	(5,489)	(17)%
Legal costs	2,296	2,293	2,792	3	0%	(499)	(18)%
Facility costs	11,425	7,675	2,466	3,750	49%	5,209	211%
Non-cash stock-based compensation	9,585	10,224	11,761	(639)	(6)%	(1,537)	(13)%
Total selling, general and administrative	$ 79,256	$ 74,986	$ 64,770	$ 4,270	6%	$ 10,216	16%

2020 versus 2019

The increase in compensation and related personnel costs was due to higher headcount resulting from the conversion of the external sales force to our employees effective April 1, 2019, offset by the decrease in business travel due to COVID-19 travel restrictions.

Outside services decreased due to the conversion of the external sales force to our employees effective April 1, 2019 and decrease in costs related to HEPLISAV-B post-marketing studies due to earlier completion of certain milestones in 2019. The decrease was offset by the $2.5 million payment to Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”) in connection with the sale of our immuno-oncology compound, SD-101 and an overall increase in costs for sales and marketing activities. The $2.5 million payment was required under our agreement with Holdings entered into in November 2009.

Facility costs, which are primarily comprised of occupancy and related expenses, increased primarily due to higher overhead allocation to selling, general and administrative functions.

Non-cash stock-based compensation decreased due to the retirement of our former CEO in August 2019 and included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020. The decrease was partially offset by the increase in headcount.

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. Non-cash stock-based compensation decreased compared to the prior period due to the timing of vesting of certain stock awards granted in 2017.

Gain on Sale of Assets

In July 2020, we sold assets related to our immuno-oncology compound, SD-101, which included intellectual property, clinical and non-clinical data, regulatory filings, clinical supply inventory and certain contracts to TriSalus. Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction and $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound.

In the third quarter of 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, net of transaction costs.

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 and includes realized gains on investments. Interest expense includes the stated interest and accretion of discount and end of term fee related to our long-term debt agreement. 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 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 2019 to 2020		Increase (Decrease) from 2018 to 2019	
	2020	2019	2018	$	%	$	%
Interest income	$ 1,260	$ 3,370	$ 3,828	$ (2,110)	(63)%	$ (458)	(12)%
Interest expense	$ (19,062)	$ (16,977)	$ (9,338)	$ 2,085	12%	$ 7,639	82%
Sublease income	$ 7,706	$ 2,619	$ -	$ 5,087	194%	$ 2,619	NM
Change in fair value of warrant liability	$ 4,124	$ (7,500)	$ -	$ 11,624	155%	$ 7,500	NM
Other	$ (897)	$ 731	$ (70)	$ (1,628)	(223)%	$ 801	1,144%

NM = Not meaningful

2020 versus 2019

Interest income decreased primarily due to lower yields on our marketable securities portfolio. 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”). Sublease income increased in connection with our sublease of office and laboratory space located at 5959 Horton Street, Emeryville, California to a third party in July 2019. The change in the fair value of the warrant liability was primarily due to a decrease in our stock price. The change in other was primarily due to foreign currency transactions and related fluctuations in the value of the Euro compared to the U.S. dollar.

2019 versus 2018

Interest expense increased due to the borrowing of the remaining $75.0 million in March 2019 under the Loan Agreement. 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 in July 2019. The change in the fair value of the warrant liability was primarily due to increase in our stock price. The change in other was 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, 2020, we had $165.0 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, 2020, and anticipated revenues from HEPLISAV-B and CpG 1018 will be sufficient to fund our operations for at least the next 12 months from the date of this filing.

Pursuant to our supply agreement with Valneva, in the fourth quarter of 2020, we received payments from Valneva totaling $20.0 million and issued an invoice to Valneva for $17.1 million for advanced payment to purchase specified quantities of CpG 1018 adjuvant in the first half of 2021. We recorded the total amount of $37.1 million as deferred revenue in our consolidated balance sheets as of December 31, 2020.

In February 2018, we entered into a term loan agreement with CRG Servicing LLC. At December 31, 2020, the principal amount of the term loan was $180.9 million, excluding debt discount of $1.1 million. The loan and the related unpaid interest and fees are due in December 2023.

In May 2020, we completed an underwritten public offering of 16,100,000 shares of our common stock at a public offering price of $5.00 per share. The net proceeds from this offering were approximately $75.4 million, after deducting the underwriting discount and other offering expenses.

For the year ended December 31, 2020, we sold 8,005,467 shares of our common stock and received net cash proceeds of $32.3 million pursuant to a 2017 At Market Sales Agreement with Cowen and Company, LLC ("2017 ATM Agreement") that terminated in August 2020.

On August 6, 2020, we entered into an at-the-market Sales Agreement (the "2020 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 of up to $150 million through Cowen as our sales agent. For the year ended December 31, 2020, we received net cash proceeds of $0.8 million resulting from sales of 109,176 shares of our common stock pursuant to the 2020 ATM Agreement. As of December 31, 2020, we had $149.1 million remaining under the 2020 ATM Agreement. Subsequent to December 31, 2020 and through February 22, 2021, we sold 2,299,952 shares of common stock for net proceeds of $22.7 million under the 2020 ATM Agreement.

We expect to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B and CpG 1018. 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. 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.

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. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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.

2020 versus 2019

During the year ended December 31, 2020, we used $92.3 million of cash for our operations primarily due to our net loss of $75.2 million, of which $21.6 million consisted of non-cash items which included stock-based compensation, depreciation and amortization, change in fair value of warrant liability, amortization of right-of-use assets, non-cash interest expense, amortization of intangible assets and accretion and amortization on marketable securities. By comparison, 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. Cash used in our operations during 2020 decreased by $29.0 million. For the year ended December 31, 2020, we received tenant improvement reimbursements from the landlord of 5959 Horton Street totaling $1.1 million, invested approximately $22.4 million in HEPLISAV-B inventory and approximately $30.4 million to scale up CpG 1018 production. Net cash used in operating activities is also impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the year ended December 31, 2020 and 2019, net cash used in investing activities was $26.5 million and $42.8 million, respectively. Cash used in investing activities during 2020 included $22.3 million of net purchases of marketable securities compared to $13.4 million of net purchases of marketable securities during 2019. During each of 2020 and 2019, we paid $7.0 million of sublicense payment to Merck. Cash used in net purchases of property plant and equipment decreased by $18.3 million during 2020 compared 2019. The decrease was, primarily, due to the installation of facility improvements in 2019. In addition, in 2020, we received $6.9 million from the sale of SD-101 assets, net of transaction costs.

During the year ended December 31, 2020 and 2019, net cash provided by financing activities was $109.5 million and $154.4 million, respectively. Cash provided by financing activities for 2020 included net proceeds of $75.4 million from our underwritten public offering in May 2020, $32.3 million from our, now terminated, 2017 ATM Agreement and $0.8 million from our 2020 ATM Agreement. 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.

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.

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2020 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations:	**Total**	**2021**	**2022-2023**	**2024-2025**	**2026 and Thereafter**
Operating leases	$ 60,616	$ 6,942	$ 11,671	$ 11,243	$ 30,760
Long-term debt obligation	188,141	-	188,141	-	-
Purchase commitments	21,948	21,948	-	-	-
Total contractual obligations	$ 270,705	$ 28,890	$ 199,812	$ 11,243	$ 30,760

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, 2020, we are obligated to make lease payments totaling $1.8 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, 2020, we are obligated to make lease payments totaling $53.6 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, 2020, we are obligated to make lease payments totaling $4.2 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, 2020 and is collateralized by a certificate of deposit for €0.2 million which has been included in restricted cash in the consolidated balance sheets as of December 31, 2020 and 2019.

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, 2020, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $180.9 million, net of debt discount of $1.1 million. Included in our total contractual obligations of $188.1 million is the principal amount of $175.0 million, paid-in-kind interest of $5.9 million and the backend facility fee of $7.2 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B, CpG 1018 adjuvant and for clinical research. As of December 31, 2020, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 and for clinical research totaled $21.7 million.

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. As of December 31, 2020, our non-cancelable obligation for services and materials provided by these organizations totaled $0.3 million.

In conjunction with our agreement 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. In July 2020, we sold assets related to our SD-101 compound to TriSalus. We are obligated to pay Holdings 50% of the contingent pre-commercialization milestone payments that we may receive under the Asset Purchase Agreement. We paid $2.5 million to Holdings in August 2020. No liability has been recorded under this agreement as of December 31, 2020.

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 $1.2 million or $1.5 million, respectively.

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

Foreign Currency Risk

We have certain investments outside the U.S. for the operations of Dynavax GmbH and Dynavax India LLP with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2020 was $0.2 million primarily related to the translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2020, 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Reserves for returns on product revenue

Description of the Matter	During the year ended December 31, 2020, the Company's net product revenues were $39.3 million. As explained in Note 2 of the consolidated financial statements, revenue from product sales includes estimates of variable consideration for which reserves are established, including reserves for product returns. Auditing the Company's measurement of reserves for product returns under its contracts with wholesalers and specialty distributors (collectively, "Customers") was challenging because (1) the calculation involves management assumptions about inventory remaining in the distribution channel (i.e., units held by Customers) as of the balance sheet date that could be subject to return in future periods under the Company's returns policy, and (2) the Company has limited returns history on which to base its assumptions.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls that identified risks related to the Company's process used to determine reserves for returns on product revenue. For example, we tested controls over management's review of the completeness and accuracy of the data used in the process, the assumptions about Customers reorder patterns and units in the channel as of the balance sheet date. To test the Company's reserves for returns on product revenue, our audit procedures included, among other procedures, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the assumptions used by management to estimate its reserves. To test management's assumptions, we inspected agreements with significant Customers to validate the rights of return policy, obtained written representations from members of the commercial and sales functions regarding changes to the terms and conditions reported to the legal and accounting departments, examined credit memos issued during and after year end for unusual items or trends not consistent with the Company's analysis of product returns, performed revenue cutoff testing at period end to assess whether there were unusual trends that should have been considered in the Company analysis of product returns, compared the shipment reports to Customers sell through information to assess the extent of inventory in the distribution channel and examined Customers reorder information. We also performed sensitivity analyses over the Company's return rate to assess the effect of changes in assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

San Francisco, California

February 25, 2021

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 32,073	$ 39,884
Marketable securities available-for-sale	132,963	111,171
Accounts and other receivables, net	22,661	8,886
Inventories, net	63,689	41,332
Prepaid manufacturing	29,423	-
Prepaid expenses and other current assets	9,206	7,380
Total current assets	290,015	208,653
Property and equipment, net	30,567	32,022
Intangible assets, net	-	2,500
Operating lease right-of-use assets	26,583	30,252
Goodwill	2,297	2,081
Restricted cash	237	216
Other assets	3,573	3,344
Total assets	$ 353,272	$ 279,068
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,312	$ 9,278
Accrued research and development	2,805	4,120
Accrued liabilities	19,099	14,802
Warrant liability	10,736	14,860
Deferred revenue	38,212	-
Other current liabilities	3,247	9,987
Total current liabilities	77,411	53,047
Long-term debt, net of debt discount of $1,094 and $1,394 at December 31, 2020 and 2019, respectively	179,811	178,601
Long-term portion of lease liabilities	34,789	37,845
Other long-term liabilities	2,568	1,285
Total liabilities	294,579	270,778
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 — 4 shares and 5 shares at December 31, 2020 and 2019, respectively		
Common stock: $0.001 par value; 278,000 shares and 139,000 shares authorized at December 31, 2020 and 2019, respectively; 110,190 shares and 83,871 shares issued and outstanding at December 31, 2020 and 2019, respectively	110	84
Additional paid-in capital	1,352,374	1,229,417
Accumulated other comprehensive gain (loss)	273	(2,387)
Accumulated deficit	(1,294,064)	(1,218,824)
Total stockholders' equity	58,693	8,290
Total liabilities and stockholders' equity	$ 353,272	$ 279,068

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2020	**2019**	**2018**
Revenues:			
Product revenue, net	$ 39,307	$ 34,644	$ 6,812
Other revenue	7,244	575	1,386
Total revenues	46,551	35,219	8,198
Operating expenses:			
Cost of sales - product	11,410	10,172	10,934
Cost of sales - amortization of intangible assets	2,500	9,217	10,862
Research and development	28,607	62,331	74,951
Selling, general and administrative	79,256	74,986	64,770
Gain on sale of assets (Note 6)	(6,851)	-	-
Restructuring	-	13,356	-
Total operating expenses	114,922	170,062	161,517
Loss from operations	(68,371)	(134,843)	(153,319)
Other income (expense):			
Interest income	1,260	3,370	3,828
Interest expense	(19,062)	(16,977)	(9,338)
Sublease income	7,706	2,619	-
Change in fair value of warrant liability (Note 14)	4,124	(7,500)	-
Other	(897)	731	(70)
Net loss	(75,240)	(152,600)	(158,899)
Preferred stock deemed dividend	-	(3,267)	-
Net loss allocable to common stockholders	$ (75,240)	$ (155,867)	$ (158,899)
Basic net loss per share allocable to common stockholders	$ (0.75)	$ (2.16)	$ (2.55)
Weighted average shares used to compute basic net loss per share allocable to common stockholders	100,753	72,024	62,362
Diluted net loss per share allocable to common stockholders	$ (0.78)	$ (2.16)	$ (2.55)
Weighted average shares used to compute diluted net loss per share allocable to common stockholders	101,504	72,024	62,362

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Net loss	$ (75,240)	$ (152,600)	$ (158,899)
Other comprehensive income (loss), net of tax:			
Reclassification of realized gain on available-for-sale securities recognized in interest income	(21)	-	-
Change in unrealized gain (loss) on marketable securities available-for-sale	(20)	140	12
Cumulative foreign currency translation adjustments	2,701	(512)	(1,146)
Total other comprehensive income (loss)	2,660	(372)	(1,134)
Total comprehensive loss	$ (72,580)	$ (152,972)	$ (160,033)

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, 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
Conversion of Preferred Stock	700	1	(1)	-	-	-	-	1
Issuance of common stock upon exercise of stock options and restricted stock awards, net	1,209	1	-	-	288	-	-	289
Issuance of common stock under Employee Stock Purchase Plan	195	-	-	-	672	-	-	672
Issuance of common stock, net of issuance costs, in conjunction with an underwritten public offering and an At Market Sales Agreement (see Note 14)	24,215	24	-	-	108,513	-	-	108,537
Stock compensation expense	-	-	-	-	13,484	-	-	13,484
Total other comprehensive loss	-	-	-	-	-	2,660	-	2,660
Net loss	-	-	-	-	-	-	(75,240)	(75,240)
Balances at December 31, 2020	110,190	$ 110	4	$ -	$ 1,352,374	$ 273	$ (1,294,064)	$ 58,693

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Operating activities			
Net loss	$ (75,240)	$ (152,600)	$ (158,899)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,273	8,938	3,621
Amortization of right-of-use assets	2,562	3,375	-
(Gain) loss on disposal of property and equipment and from lease termination	(98)	18	98
Amortization of premiums (accretion of discounts) on marketable securities	535	(1,462)	(1,559)
Realized gain on available-for-sale securities	(57)	-	-
Change in fair value of warrant liability	(4,124)	7,500	-
Stock compensation expense	13,484	25,456	23,478
Cost of sales - amortization of intangible assets	2,500	9,217	10,862
Non-cash interest expense	2,542	4,973	2,755
Tenant improvements provided by the landlord	1,137	6,999	-
Gain on sale of assets	(6,851)	-	-
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(13,775)	(5,182)	(2,850)
Inventories, net	(22,357)	(22,310)	(18,710)
Prepaid manufacturing	(29,423)	-	-
Prepaid expenses and other current assets	(1,826)	(1,278)	(2,405)
Other assets	(229)	1,632	(3,706)
Accounts payable	(3,448)	4,848	3,417
Lease liabilities	(2,872)	(2,000)	-
Deferred revenue	38,212	-	-
Accrued and other liabilities	2,804	(9,376)	12,597
Net cash used in operating activities	(92,251)	(121,252)	(131,301)
Investing activities			
Acquisition of technology licenses	(7,000)	(7,000)	(11,000)
Purchases of marketable securities	(201,786)	(215,191)	(213,804)
Proceeds from maturities and redemptions of marketable securities	148,565	201,810	284,457
Proceeds from sales of marketable securities	30,910	-	-
Purchases of property and equipment, net	(4,072)	(22,401)	(4,187)
Proceeds from sale of assets, net of transaction costs	6,851	-	-
Net cash (used in) provided by investing activities	(26,532)	(42,782)	55,466
Financing activities			
Proceeds from long-term debt, net	-	74,250	99,000
Proceeds from issuances of common stock, net	108,538	65,948	-
Proceeds from issuances of preferred stock, net	-	13,586	-
Proceeds (tax withholding) from exercise of stock options and restricted stock awards, net	289	2	(523)
Proceeds from Employee Stock Purchase Plan	672	565	594
Net cash provided by financing activities	109,499	154,351	99,071
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,494	(184)	(482)
Net (decrease) increase in cash, cash equivalents and restricted cash	(7,790)	(9,867)	22,754
Cash, cash equivalents and restricted cash at beginning of year	40,100	49,967	27,213
Cash, cash equivalents and restricted cash at end of year	$ 32,310	$ 40,100	$ 49,967
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 16,541	$ 12,147	$ 6,583
Non-cash investing and financing activities:			
Non-cash acquisition of technology license	$ -	$ -	$ 12,773
Purchases of property and equipment, not yet paid	$ 361	$ 2,698	$ 920
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 focused on developing and commercializing novel vaccines. Our first marketed 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 also manufacture and sell CpG 1018, the adjuvant used in HEPLISAV-B. We are working to develop CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. 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 subsidiaries, Dynavax GmbH located in Düsseldorf, Germany and Dynavax India LLP in India. 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, 2020, we had cash, cash equivalents and marketable securities of $165.0 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 and development of our CpG 1018 adjuvant. 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, 2020, and anticipated revenues from HEPLISAV-B and CpG 1018 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 subsidiaries, Dynavax GmbH and Dynavax India LLP. 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.

As of December 31, 2020 and 2019, the cumulative translation adjustments balance was $0.2 million and $(2.5) million, respectively, primarily related to the translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. For the years ended December 31, 2020, 2019 and 2018, we reported an unrealized gain (loss) of $2.7 million, $(0.5) million and $(1.1) 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, 2020, 2019 and 2018, we reported a (loss) gain of $(0.8) million, $0.2 million and $0.3 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 years ended December 31, 2020, 2019 and 2018, 77%, 100% and 83%, respectively, of our revenues were earned in the United States. As of December 31, 2020 and 2019, 57% and 62%, 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 and CpG 1018.

We sell HEPLISAV-B to a limited number of wholesalers and specialty distributors in the U.S. All of our HEPLISAV-B revenue is from these customers. For the years ended December 31, 2020, 2019 and 2018, our three largest customers collectively represented approximately 61%, 62% and 68% of our HEPLISAV-B product revenue, respectively. All of our CpG 1018 sales were outside the U.S.

As of December 31, 2020 and 2019, our three largest customers collectively represented approximately 86% and 76% of our HEPLISAV-B trade receivable balance.

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("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. For the year ended December 31, 2020 and 2019, there were no inventory reserves recognized. During 2018, we recorded $1.0 million in inventory reserves, which is included in cost of sales – product.

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, 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

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.

The operating lease right-of-use assets also include any lease payments made and exclude any lease incentives. 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. We have also elected the practical expedient to not separate lease components from non-lease components.

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, the amount by which the carrying amount exceeds the reporting unit's fair value is 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 – HEPLISAV-B

We sell HEPLISAV-B 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 significant 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. We evaluate our estimates of variable considerations including, but not limited to, product returns, chargebacks and rebates, periodically or when there is an event or change in circumstances that may indicate that our estimates may change. During the fourth quarter of 2020, based on an analysis of historical product returns and customer ordering patterns, we decreased our returns reserve resulting in an increase in HEPLISAV-B product revenue, net of approximately $0.8 million. There were 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.

Product Revenue, Net – CpG 1018

We also sell our novel adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. We have determined that our collaboration partners meet the definition of customers under ASC 606. Therefore, we accounted for our CpG 1018 sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer. Because the timing between the recognition of revenue for product sales and the receipt of payment is less than one year, there is no significant financing component on the related receivables.

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 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.

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. Collaboration and 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, 2020 and 2019. 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. For public business entities, excluding smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2019. Furthermore, the one-time determination of whether an entity is eligible to be a smaller reporting company shall be based on an entity's most recent determination as of November 15, 2019, in accordance with SEC regulations. Because we were a smaller reporting company based on the most recent determination as of November 15, 2019, this ASU and its subsequent updates, will be 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 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 adopted this ASU on January 1, 2021 and the adoption of this standard did not have a material impact on our consolidated financial statements.

Accounting Standards Update 2020-06

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2021 with early adoption permitted. We are currently evaluating the impact this standard will have on our condensed 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, 2020 and 2019.

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, 2020				
Assets				
Money market funds	$ 23,128	$ -	$ -	$ 23,128
U.S. treasuries	-	32,579	-	32,579
U.S. government agency securities	-	40,321	-	40,321
Corporate debt securities	-	61,063	-	61,063
Total assets	$ 23,128	$ 133,963	$ -	$ 157,091
Liabilities				
Warrant liability	$ -	$ -	$ 10,736	$ 10,736

	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

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, 2020, we used the following key assumptions to estimate the fair value of warrant liability:

Number of shares	5,841,250
Expected term	1.1 years
Expected volatility	1.0
Risk-free interest rate	0.1%
Dividend yield	0%

The following table provides a summary of changes in the fair value warrant liability for year ended December 31, 2020 and 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
Decrease in estimated fair value of warrant liability upon revaluation	(4,124)
Balance at December 31, 2020	$ 10,736

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		
	2020	**2019**	**2018**
Cash and cash equivalents	$ 32,073	$ 39,884	$ 49,348
Restricted cash	237	216	619
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 32,310	$ 40,100	$ 49,967

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, 2020				
Cash and cash equivalents:				
Cash	$ 7,945	$ -	$ -	$ 7,945
Money market funds	23,128	-	-	23,128
Corporate debt securities	1,000	-	-	1,000
Total cash and cash equivalents	32,073	-	-	32,073
Marketable securities available-for-sale:				
U.S. treasuries	32,548	31	-	32,579
U.S. government agency securities	40,313	14	(6)	40,321
Corporate debt securities	60,071	3	(11)	60,063
Total marketable securities available-for-sale	132,932	48	(17)	132,963
Total cash, cash equivalents and marketable securities	$ 165,005	$ 48	$ (17)	$ 165,036
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

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

	December 31, 2020	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 122,156	$ 122,181
Mature after one year through two years	10,776	10,782
	$ 132,932	$ 132,963

For the year ended December 31, 2020, there were gross realized gains on investments of $0.1 million and no gross realized losses. There were no gross realized gains or losses on investments for each of the year ended December 31, 2019 and 2018. Realized gains are included in interest income in the consolidated statements of operations. All investments with unrealized losses at December 31, 2020 have been in a loss position for less than twelve months. We do not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis. To date, there have been no declines in fair value that have been identified as other than temporary.

5. Inventories, net

The following table presents inventories, net (in thousands):

	December 31	
	2020	2019
Raw materials	$ 25,121	$ 15,198
Work-in-process	30,293	22,890
Finished goods	8,275	3,244
Total	$ 63,689	$ 41,332

As of December 31, 2020, prepaid manufacturing on the consolidated balance sheets represents prepayments totaling $29.4 million made to a third-party manufacturer to produce CpG 1018 to fulfil our collaborators' orders which we expect to be utilized in the manufacturing process and/or sold within the next twelve months. See Note 10.

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,	
	2020	**2019**
Intangible assets	$ 19,773	$ 19,773
Less accumulated amortization	(19,773)	(17,273)
Total	$ -	$ 2,500

We recorded cost of sales - amortization of intangible assets related to capitalized sublicense payments to Merck, Sharp & Dohme Corp. ("Merck") that we capitalized upon FDA approval of HEPLISAV-B in November 2017. See Note 10. Cost of sales – amortization of intangible assets for the year ended 2020 and 2019 was $2.5 million and $9.2 million, respectively. At December 31, 2020, intangible assets related to Merck has been fully amortized. No impairment of intangible assets has been identified during the years presented.

Sale of SD-101 Program

In May 2019, we announced a strategic restructuring to focus on our vaccine business and curtail our investment in our immuno-oncology programs. In July 2020, we sold assets related to our immuno-oncology compound, SD-101, which included intellectual property, clinical and non-clinical data, regulatory filings, clinical supply inventory and certain contracts to Surefire Medical Inc. d/b/a TriSalus Life Sciences ("TriSalus"). Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction and $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound. In connection with our agreement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC ("Holdings") in November 2009, we paid $2.5 million to Holdings in August 2020. See Note 9.

For the year ended December 31, 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, based on the amount of consideration received, net of any transaction costs. The $2.5 million payment to Holdings was included in selling, general and administrative expense in our consolidated statement of operations.

7. Property and Equipment, net

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

	Estimated Useful Life (In years)	**December 31,**	
		2020	**2019**
Manufacturing equipment	5-14	$ 13,884	$ 11,484
Lab equipment	5-13	2,888	2,522
Computer equipment	3	5,255	5,009
Furniture and fixtures	3-13	2,510	1,934
Leasehold improvements	2-12	28,417	24,724
Assets in progress		1,024	4,336
		53,978	50,009
Less accumulated depreciation and amortization		(23,411)	(17,987)
Total		$ 30,567	$ 32,022

Depreciation and amortization expense on property and equipment was $4.3 million, $8.9 million and $3.6 million for the years ended December 31, 2020, 2019 and 2018, 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,	
	2020	2019
Payroll and related expenses	$ 8,684	$ 6,653
Revenue reserve accruals	6,040	3,893
Third party research expenses	1,963	2,308
Third party development expenses	842	505
Restructuring liability	-	675
Other accrued liabilities	4,375	4,888
Total	$ 21,904	$ 18,922

9. Commitments and Contingencies

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 $8.1 million was received through December 31, 2020. 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, 2020 and 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 years ended December 31, 2020 and 2019, we recognized $7.7 million and $2.6 million, respectively 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,		
	2020	2019	2018
Operating lease expense	$ 6,267	$ 6,886	$ 3,953

Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2020 and 2019 was $6.9 million and $5.5 million, respectively and were included in change in lease liabilities in our consolidated statement of cash flows.

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

	December 31, 2020	December 31, 2019
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 3,247	$ 3,039
Long-term portion of lease liabilities	34,789	37,845
Total operating lease liabilities	$ 38,036	$ 40,884

At December 31, 2020, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2021	$ 5,201	$ 6,942
2022	5,357	6,268
2023	5,518	5,403
2024	5,684	5,547
2025	5,854	5,696
Thereafter	33,742	30,760
Total	$ 61,356	60,616
Less:		
Present value adjustment		(22,580)
Total		$ 38,036

The weighted average remaining lease term and the weighted average discount rate used to determine the operating lease liability were as follows:

	December 31, 2020	December 31, 2019
Weighted average remaining lease term	9.1 years	9.7 years
Weighted average discount rate	10.1%	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, 2020, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans. Included in our total contractual obligations of $188.1 million is the principal amount of $175.0 million, paid-in-kind interest of $5.9 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.

As of December 31, 2020, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 and for clinical research totaled $21.7 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, 2020 and is collateralized by a certificate of deposit for €0.2 million, which has been included in restricted cash in the consolidated balance sheets as of December 31, 2020 and 2019.

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. As of December 31, 2020, our non-cancelable obligation for services and materials provided by these organizations totaled $0.3 million.

We provided $0.1 million of guarantee as of December 31, 2020 in the form of a surety bond issued to support a certain license which requires a surety bond to ensure our compliance with a certain state's requirements. We would only be liable for any penalty of up to the guaranteed amount in the event of a non-compliance, of which the probability is remote.

In conjunction with our agreement with 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. In July 2020, we sold assets related to our SD-101 compound to TriSalus. See Note 6. We paid $2.5 million to Holdings in August 2020. We are obligated to pay Holdings 50% of the contingent pre-commercialization milestone payments that we may receive under the Asset Purchase Agreement. No liability has been recorded under this agreement as of December 31, 2020.

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

Coalition for Epidemic Preparedness Innovations

In September 2020, we entered into a Reservation Agreement for the Provision of Goods (the "Reservation Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") to make available specified quantities of CpG 1018 adjuvant, for purchases at certain prices, to CEPI and its COVID-19 vaccine development partners ("CEPI Partners"). Payments received under the Reservation Agreement are considered an exchange for our CpG 1018 adjuvant which is an output of our ordinary activities. As such, we account for the arrangement under the scope of ASC 606. Payments are recorded as deferred revenue and recognized as revenue in the period when we satisfy our performance obligation to deliver CpG 1018 ordered or when CEPI's right to place an order expires. Pursuant to the Reservation Agreement, we received $6.3 million from CEPI in September 2020 for production scale-up and a fourth quarter 2020 reservation fee.

In October 2020, CEPI terminated the Reservation Agreement and its right to place an order expired. Therefore, we recognized $6.3 million as other revenue in the fourth quarter of 2020.

Valneva SE

In April 2020, we entered into a Collaboration Agreement, as amended, with Valneva Scotland Limited ("Valneva") to provide CpG 1018 adjuvant for use in the development of Valneva's COVID-19 vaccine candidate. Then, in July 2020, we entered into a Clinical Collaboration Agreement, as amended, to provide additional quantities of CpG 1018 adjuvant. In September 2020, we entered into a Supply Agreement ("Supply Agreement") with Valneva to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the commercialization of Valneva's COVID-19 vaccine candidate.

We concluded that the Collaboration Agreement and the Supply Agreement were entered into at or near the same time, with the same customer and were negotiated as a package with a single commercial objective, that is the provision of CpG 1018 adjuvant to Valneva. Therefore, the Collaboration Agreement and the Supply Agreement should be combined and accounted for as a single arrangement.

Pursuant to our supply agreement with Valneva, in the fourth quarter of 2020, we received payments from Valneva totaling $20.0 million and issued an invoice to Valneva for $17.1 million for advanced payment to purchase specified quantities of CpG 1018 adjuvant in the first half of 2021. We recorded the total amount of $37.1 million as deferred revenue in our consolidated balance sheets as of December 31, 2020.

Bill & Melinda Gates Foundation Grant Agreement

In July 2020, we entered into a grant agreement (the "Grant Agreement") with Bill & Melinda Gates Foundation ("BMGF"), under which we were awarded a grant of up to $3.4 million to scale up production of our CpG 1018 adjuvant to support the global COVID-19 response (the "Project") and we received $1.2 million of the grant from BMGF which we accounted for as deferred revenue in our consolidated balance sheets at December 31, 2020. Any grant funds, plus any income, that have not been used for, or committed to, the Project must be returned promptly to BMGF upon expiration or termination of the Grant Agreement.

We and BMGF had also planned to execute a Global Access and Strategy/Commitment Agreement ("GASC Agreement") in connection with the Grant Agreement. Upon execution of the GASC Agreement, we would receive the remaining $2.2 million in grant funding. As of February 25, 2021, the GASC Agreement has not been executed and if it is not executed we will not receive the remaining grant funding.

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 years ended December 31, 2020, 2019 and 2018, we recognized collaboration revenue of $0.9 million, $0.1 million and $1.4 million, respectively.

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 were 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 Sublicense Agreement expired in April 2020, at which time the license became perpetual, irrevocable, fully paid-up and royalty free. As of December 31, 2020, the intangible asset has been fully amortized. At December 31, 2019, the intangible asset, net balance was $2.5 million. See Note 6.

11. Long-Term Debt

Long-Term Debt

On February 20, 2018, we entered into a $175.0 million Loan Agreement with CRG Servicing LLC ("CRG"). 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, 2020, 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, 2020, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $180.9 million, net of debt discount of $1.1 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 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.

In November 2020, we entered into a third amendment to the Loan Agreement (the "Third Amendment"). The Third Amendment modified the annual net sales threshold requirement to include sales of CpG 1018 and removed the annual net sales threshold requirement for the twelve-month period beginning July 1, 2020 and ending on June 30, 2021.

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 and CpG 1018.

We recorded $19.1 million, $16.5 million and $8.8 million of interest expense related to the Term Loans during the year ended December 31, 2020, 2019 and 2018, respectively.

12. Revenue Recognition

Our product revenue, net consisted of the following:

	Year Ended December 31		
	2020	2019	2018
HEPLISAV-B	$ 36,030	$ 34,644	$ 6,812
CpG 1018	3,277	-	-
Total	$ 39,307	$ 34,644	$ 6,812

The following table summarizes balances and activities in HEPLISAV-B product revenue allowance and reserve categories for the year ended December 31, 2020 and 2019 (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, 2020:				
Accounts receivable reserves(1)	$ 2,701	$ 11,417	$ (11,282)	$ 2,836
Revenue reserve accruals(2)	$ 3,893	$ 6,694	$ (4,547)	$ 6,040
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

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

	Year Ended December 31,		
	2020	2019	2018
Numerator			
Net loss	$ (75,240)	$ (152,600)	$ (158,899)
Preferred stock deemed dividend	-	(3,267)	-
Net loss allocable to common stockholders, basic	(75,240)	(155,867)	(158,899)
Removal of change in fair value of warrant liability	(4,124)	-	-
Net loss allocable to common stockholders, diluted	$ (79,364)	$ (155,867)	$ (158,899)
Denominator			
Weighted average shares used to compute net loss allocable to common stockholders per share, basic	100,753	72,024	62,362
Effect of dilutive warrants	751	-	-
Weighted average shares used to compute net loss allocable to common stockholders per share, diluted	101,504	72,024	62,362

The following were excluded from the calculation of diluted net loss per share as the effect of their inclusion would have been anti-dilutive:

	December 31,		
	2020	2019	2018
Outstanding securities not included in diluted net loss per share calculation (in thousands):			
Stock options and stock awards	10,299	9,789	7,344
Series B Convertible Preferred Stock (as converted to common stock)	4,140	4,840	-
Warrants (as exercisable into common stock)	-	5,841	-

14. Common Stock

Common Stock Outstanding

As of December 31, 2020, there were 110,189,859 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 (Bain Capital Life Sciences) 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 (together, "Bain Life Sciences Funds"). Bain Capital Life Sciences is the general partner of Bain Life Sciences Funds. 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 March 11, 2020, we entered into a warrant exchange agreement with Bain Life Sciences Funds pursuant to which we agreed that we would, upon future notice from Bain Life Sciences Funds, exchange all or a portion of the common stock warrants held by Bain Life Sciences Funds for warrants to purchase a new Series C convertible preferred stock ("Series C Warrants"). 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 Preferred Stock. As of December 31, 2020, Bain Life Sciences Funds have not exercised their rights to exchange common stock warrants with Series C Warrants.

In May 2020, we completed an underwritten public offering of 16,100,000 shares of our common stock, par value $0.001 per share, including 2,100,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters. All of the shares were offered at a price to the public of $5.00 per share. The net proceeds to us from this offering were approximately $75.4 million, after deducting the underwriting discount and other offering expenses payable by us. Bain Life Sciences Funds purchased 1,000,000 shares of common stock in the underwritten public offering. The participation by Bain Life Sciences Funds was on the same terms as the other investors in the offering.

For year ended December 31, 2020, we sold 8,005,467 shares of our common stock and received net cash proceeds of $32.3 million pursuant to a 2017 At Market Sales Agreement ("2017 ATM Agreement") with Cowen and Company, LLC ("Cowen") that terminated in August 2020.

On August 6, 2020, we entered into an at-the-market Sales Agreement (the "2020 ATM Agreement") with 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 of up to $150 million through Cowen as our sales agent. We agreed to pay Cowen a commission of up to 3% of the gross sales proceeds of any common stock sold through Cowen under the 2020 ATM Agreement. For the year ended December 31, 2020, we received net cash proceeds of $0.8 million resulting from sales of 109,176 shares of our common stock pursuant to the 2020 ATM Agreement. As of December 31, 2020, we had $149.1 million remaining under the 2020 ATM Agreement. Subsequent to December 31, 2020 and through February 22, 2021, we sold 2,299,952 shares of common stock for net proceeds of $22.7 million under the 2020 ATM Agreement.

Preferred Stock Outstanding

As of December 31, 2020, there were 4,140 shares of Series B Preferred Stock outstanding.

In the second quarter of 2020, 700 shares of our Series B Preferred Stock were converted into 700,000 shares of common stock.

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, 2020, 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, 2020 (in thousands)
August 12, 2019	5,841	February 12, 2022	$ 4.50	5,841

In February 2021, 750,000 of our common stock warrants were exercised.

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, 2020 and 2019, the estimated fair value of warrant liability was $10.7 million and $14.9 million, respectively. For the year ended December 31, 2020, we recognized $4.1 million decrease in the estimated fair value of warrant liability as income in other income (expense) in our consolidated statements of operations. For the year ended December 31, 2019, we recognized $7.5 million increase in the estimated fair value of warrant liability as a loss in other income (expense) 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 28, 2020 and 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 7,600,000 and 2,300,000, respectively. 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 22,517,869.

In January 2021, we adopted the Dynavax Technologies Corporation 2021 Inducement Award Plan, pursuant to which we reserved 1,500,000 shares of common stock for issuance under the plan to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company.

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, 2020, there were 8,349,853 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, 2019	8,006	$ 13.86		
Options granted	2,003	5.76		
Options exercised	(72)	4.20		
Options cancelled:				
Options forfeited (unvested)	(356)	7.24		
Options expired (vested)	(1,076)	19.75		
Balance at December 31, 2020	8,505	$ 11.57	4.25	$ 616
Vested and expected to vest at December 31, 2020	8,314	$ 11.69	4.21	$ 607
Exercisable at December 31, 2020	5,551	$ 14.13	3.35	$ 516

The total intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018 was $0.1 million, $26,000 and $0.2 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2020, 2019 and 2018 was $13.8 million, $19.5 million and $8.1 million, respectively.

Our non-vested stock awards are comprised of restricted stock units granted with performance and time-based vesting criteria. A summary of the status of non-vested restricted stock units as of December 31, 2020, and activities during 2020 are summarized as follows:

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2019	1,784	$ 9.16
Granted	1,412	5.64
Vested	(1,139)	8.18
Forfeited	(263)	7.68
Non-vested as of December 31, 2020	1,794	$ 7.23

Stock-based compensation expense related to restricted stock units was approximately $4.9 million for the year ended December 31, 2020. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2020, based on our stock price on that date, was $8.0 million.

The total fair value of restricted stock units vested during the years ended December 31, 2020, 2019 and 2018 was $4.9 million, $7.9 million and $19.4 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, 2020, approximately 117,000 shares underlying stock options and approximately 247,000 restricted stock unit awards with performance-based vesting criteria were outstanding. None of the awards with performance-based vesting criteria were deemed probable as of December 31, 2020. We recognized stock-based compensation expense for awards with performance-based vesting criteria during the years ended December 31, 2020, 2019 and 2018 of $0.1 million, $0.5 million and $1.9 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,		
	2020	2019	2018	2020	2019	2018
Weighted-average fair value	$ 3.91	$ 4.58	$ 10.75	$ 2.82	$ 2.72	$ 8.30
Risk-free interest rate	1.0%	2.1%	2.5%	0.9%	1.9%	2.4%
Expected life (in years)	4.5	4.5	4.2	1.2	1.2	1.3
Expected Volatility	0.9	0.9	0.8	0.7	0.7	1.1

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 for the year ended December 31, 2020 included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020. 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,		
	2020	2019	2018
Employees and directors stock-based compensation expense	$ 13,484	$ 25,456	$ 23,478

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 1,000	$ 8,058	$ 9,604
Selling, general and administrative	9,585	10,224	11,761
Cost of sales - product	619	1,088	1,354
Inventory	2,280	1,964	759
Restructuring	-	4,122	-
Total	$ 13,484	$ 25,456	$ 23,478

As of December 31, 2020, 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 $15.9 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.8 years. Additionally, as of December 31, 2020, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $1.2 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, 2020, employees have acquired 195,334 shares of our common stock under the Purchase Plan and 255,583 shares of our common stock remained available for future purchases under the Purchase Plan.

As of December 31, 2020, the total unrecognized compensation cost related to shares of our common stock under the Purchase Plan amounted to $0.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 1 year.

16. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. The Company’s contribution to the 401(k) Plan was approximately $0.2 million, $0.3 million and $0.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

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, 2020, 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	Restructuring Costs Incurred for the Year Ended December 31, 2019
Severance and other termination benefits	$ 6,277
Stock-based compensation expense (a)	4,122
Accelerated depreciation	2,957
Total restructuring cost	$ 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, 2020 and 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
Cash payments or settlements	(675)
Balance at December 31, 2020	$ -

18. Income Taxes

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

	Year Ended December 31,		
	2020	2019	2018
U.S.	$ (76,324)	$ (154,605)	$ (160,032)
Non U.S.	1,084	2,005	1,133
Total	$ (75,240)	$ (152,600)	$ (158,899)

No income tax expense was recorded for the years ended December 31, 2020, 2019 and 2018 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,		
	2020	2019	2018
Income tax benefit at federal statutory rate	$ (15,756)	$ (32,046)	$ (33,366)
State tax	(3,194)	(3,153)	(5,591)
Business credits	(773)	(1,757)	(3,065)
Uncertain tax positions	193	5,426	-
Deferred compensation charges	809	4,600	(1,165)
Change in valuation allowance	19,009	22,715	43,134
Section 162(m) limitation	473	2,439	-
Mark-to-market of warrants	(866)	1,575	-
Other	105	201	53
Total income tax expense	$ -	$ -	$ -

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carry forwards	$ 224,161	$ 207,385
Research tax credit carry forwards	28,578	27,883
Accruals and reserves	17,264	17,312
Capitalized research costs	-	256
Other	3,250	2,437
Total deferred tax assets	273,253	255,273
Less valuation allowance	(266,100)	(247,092)
Net deferred tax assets	7,153	8,181
Deferred tax liabilities:		
Fixed assets	(275)	(275)
Operating lease right-of-use assets	(6,878)	(7,906)
Total deferred tax liabilities	(7,153)	(8,181)
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 $19.0 million and $22.3 million for the years ended December 31, 2020 and 2019, respectively, due to an increase in our deferred tax assets.

As of December 31, 2020, we had federal net operating loss carryforwards of approximately $955.0 million, which will begin to expire in the year 2021 and federal research and development tax credits of approximately $22.5 million, which expire in the years 2021 through 2040.

As of December 31, 2020, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $373.2 million, which expire in the years 2021 through 2040, and California state research and development tax credits of approximately $19.8 million, which do not expire.

As of December 31, 2020, we had net operating loss carryforwards for foreign income tax purposes of approximately $6.7 million, which do not expire.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits was $10.6 million and $10.3 million as of December 31, 2020 and 2019, 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, 2019	$ (10,322)
Tax positions related to the current year	
Additions	(243)
Reductions	-
Tax positions related to the prior year	
Additions	-
Reductions	-
Balance at December 31, 2020	$ (10,565)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2020, 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, 2020. 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 2020 and 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 2001 forward. We are subject to tax examination in Germany from 2017 forward and in India from 2018 forward.

19. Subsequent Event

CEPI Agreement

On January 29, 2021, we entered into an agreement (the "Agreement") with CEPI for the manufacture and reservation of a specified quantity of CpG 1018 ("CpG 1018 Materials"). The Agreement enables CEPI to direct the supply of CpG 1018 Materials to CEPI partner(s). CEPI partner(s) would purchase CpG 1018 Materials under separately negotiated agreements, subject to specified pricing requirements. The Agreement also allows us to sell CpG 1018 Materials to third-parties if not purchased by a CEPI partner within a defined period of time.

In exchange for reserving CpG 1018 Materials, CEPI has agreed to provide an interest-free, unsecured, forgivable loan of up to $99 million (the "Loan Amount") which is equivalent to the anticipated manufacturing costs of CpG 1018 Materials. The Loan Amount will be funded in part upon the execution of the Agreement, in part upon the exercise of CEPI's option to reserve additional quantity of CpG 1018 Materials and in part upon the release of CpG 1018 Materials. We are obligated to repay the Loan Amount, on a proportional basis, if and to the extent we receive payment for CpG 1018 Materials reserved under the Agreement. If the vaccine programs pursued by CEPI partner(s) are unsuccessful and no alternative use is found for CpG 1018 Materials reserved under the Agreement, the applicable Loan Amount will be forgiven.

Amendment to CRG Loan Agreement

On January 29, 2021, we entered into a fourth amendment to the Loan Agreement with CRG (the "Fourth Amendment"). The Fourth Amendment amended the Loan Agreement to, among other things, allow us to enter into the Agreement with CEPI and to perform our obligations thereunder.

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, 2020. 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020 and the related notes of the Company and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP
San Francisco, California
February 25, 2021

(c) Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the sections entitled "Proposal 1—Elections of Directors," "Executive Officers," "Corporate Governance" and "Delinquent Section 16(a) Reports" in our Definitive Proxy Statement in connection with the 2021 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, 2020.

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

Exhibit Number	Document	Incorporated by Reference				Filed Herewith
		Exhibit Number	Filing	Filing Date	File No.	
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 Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	May 29, 2020	001-34207	
3.11	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, 3.10 and 3.11 above					
4.3	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.4	Form of Series B Preferred Stock Certificate	4.3	10-Q	November 7, 2019	001-34207	
4.5	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	
10.6+	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+	Non-Employee Director Compensation Policy	10.2	10-Q	August 6, 2020	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 6, 2020	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	10.17	10-K	March 11, 2020	001-34207	
10.18+	President and Chief Operating Officer Letter, dated December 13, 2019, between the Company and David Novack	10.18	10-K	March 11, 2020	001-34207	
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	10.23	10-K	March 11, 2020	001-34207	

Exhibit Number	Document	Incorporated by Reference				Filed Herewith
		Exhibit Number	Filing	Filing Date	File No.	
10.24	Registration Rights Agreement, dated March 11, 2020, by and among the Company, Bain Capital Life Sciences Fund, L.P. and BCIP Life Sciences Associates, LP.	99.D	13D/A	March 12, 2020	005-80035	
10.25	Warrant Exchange Agreement, dated March 11, 2020, by and among the Company, Bain Capital Life Sciences Fund, L.P. and BCIP Life Sciences Associates, LP	99.E	13D/A	March 12, 2020	005-80035	
10.26^	Supply Agreement, dated September 11, 2020, by and among the Company, Valneva Scotland Limited and Valneva Austria GmbH	10.2	10-Q	November 5, 2020	001-34207	
10.27+	Amended and Restated Management Continuity and Severance Agreement, dated September 22, 2020, between Michael S. Ostrach and the Company	10.3	10-Q	November 5, 2020	001-34207	
10.28	Amendment No. 3 to Term Loan Agreement and Fee Letter, dated November 2, 2020, by and among Company, CRG Partners III L.P., CRG Partners III-Parallel Fund "A" L.P. and CRG Servicing LLC	10.4	10-Q	November 5, 2020	001-34207	
10.29	Sales Agreement, dated August 6, 2020, between the Company and Cowen and Company, LLC	10.3	10-Q	August 6, 2020	001-34207	
10.30+	Dynavax Technologies Corporation 2021 Inducement Award Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Grant Notice and Restricted Stock Unit Award Agreement.	10.1	8-K	January 12, 2021	001-34207	
10.31^	Agreement, dated January 29, 2021 between Company and Coalition for Epidemic Preparedness Innovations					X
10.32	Amendment No. 4 to Term Loan Agreement and Fee Letter, dated January 29, 2021, by and among Company, CRG Partners III L.P., CRG Partners III-Parallel Fund "A" L.P. and CRG Servicing LLC					X
10.33+	Kelly MacDonald Employment Letter					X
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X

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

^ Certain portions of this exhibit (indicated by asterisks) have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed. The Registrant agrees to furnish supplementally an unredacted copy of any exhibit to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

* 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: February 25, 2021

By: /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: February 25, 2021

By: /s/ JUSTIN BURGESS

Justin Burgess
Controller
(Principal Accounting Officer)

Date: February 25, 2021

Signature	Title	Date
/s/ RYAN SPENCER **Ryan Spencer**	Chief Executive Officer *(Principal Executive Officer)*	February 25, 2021
/s/ MICHAEL OSTRACH **Michael Ostrach**	Chief Financial Officer *(Principal Financial Officer)*	February 25, 2021
/s/ JUSTIN BURGESS **Justin Burgess**	Controller *(Principal Accounting Officer)*	February 25, 2021
/s/ ANDREW HACK **Andrew Hack, M.D., Ph.D.**	Chairman of the Board	February 25, 2021
/s/ FRANCIS R. CANO **Francis R. Cano, Ph.D.**	Director	February 25, 2021
/s/ JULIE EASTLAND **Julie Eastland**	Director	February 25, 2021
/s/ DANIEL L. KISNER **Daniel L. Kisner, M.D.**	Director	February 25, 2021
/s/ BRENT MACGREGOR **Brent MacGregor**	Director	February 25, 2021
/s/ PETER R. PARADISO **Peter R. Paradiso**	Director	February 25, 2021
/s/ PEGGY V. PHILLIPS **Peggy V. Phillips**	Director	February 25, 2021
/s/ NATALE S. RICCIARDI **Natale S. Ricciardi**	Director	February 25, 2021

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 278,000,000 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.

Exhibit 10.31

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

Agreement

This Agreement ("**Agreement**") is entered into as of the date of last signature by and between **Coalition for Epidemic Preparedness Innovations**, having an address of PO Box 123, Torshov, N-0412 Oslo, Norway ("**CEPI**"), and **Dynavax Technologies Corporation**, having an address of 2100 Powell Street, Suite 900, Emeryville, CA 94608, USA ("**Dynavax**"). Each of CEPI and Dynavax is referred to herein individually as a "**Party**" and are collectively referred to herein as the "**Parties**."

Recitals

Whereas, Dynavax has developed a proprietary toll-like receptor 9 (TLR9) agonist adjuvant known as CpG 1018;

Whereas, CEPI's mission is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks;

Whereas, CEPI has entered or may enter in the future into legal agreements with certain third parties (each, a "**CEPI Partner**") regarding the funding of development and manufacturing initiatives of vaccines for COVID-19;

Whereas, to further its mission, CEPI desires to advance an interest-free, forgivable, unsecured loan to cover the costs of at risk manufacture of specified quantities of the CpG 1018 adjuvant and to reserve such quantities for purchase by CEPI Partners for use in development and manufacturing of vaccines against COVID-19; and

Whereas, this Agreement sets out the legal framework under which Dynavax will manufacture specified quantities of the CpG 1018 adjuvant and reserve such quantities for purchase by CEPI Partners (collectively, the **"Project"**).

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions

As used in this Agreement, the following terms shall have the meanings set forth below.

1.1 "Additional Loan Amount" shall mean an amount equivalent to the total Manufacturing Cost of the Additional Reserved Amount as set forth in Section 3.1(a).

1.2 "Additional Reserved Material" shall have the meaning provided in Section 2.1(b).

1.3 "Applicable Laws" shall mean all national and supranational laws and regulations and other mandatory professional regulations applicable to a Party, or a Party's activities or obligations described under or pursuant to this Agreement.

1.4 **"BA"** shall mean the UK Bribery Act 2010 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the relevant government department concerning the legislation.

1.5 **"Business Day"** shall mean a day which is not a Saturday or Sunday, or a bank or public holiday in England, Norway, the USA and/or the country in which a Party is located and with regard to which country that Party is obligated hereunder to act in a specified number of Business Days.

1.6 **"CEPI Partner"** shall have the meaning provided in the Recitals to this Agreement. In addition, if a COVAX Approved Partner is accepted for inclusion as a "CEPI Partner" under Section 2.3, such COVAX Approved Partner shall be considered a CEPI Partner for purposes of this Agreement.

1.7 **"CEPI Partner Product"** shall mean a product containing or comprising a combination of CEPI Partner Vaccine and Dynavax Adjuvant (whether such Dynavax Adjuvant is formulated with the Customer Vaccine in the same vial or separately from the Customer Vaccine in an accompanying vial).

1.8 **"CEPI Partner Vaccine"** shall mean a COVID-19 vaccine being developed or commercialized by or on behalf of a CEPI Partner.

1.9 **"CEPI Third Party Code"** or **"Code"** shall mean the CEPI Third Party Code in effect at the Effective Date, which is available at https://cepi.net/wp-content/uploads/2019/10/CEPI-Third-Party-Code.pdf, together with any future amendments thereto and any new policies and procedures acceded to by the Parties.

1.10 **"CFA"** shall mean the UK Criminal Finances Act 2017 and any subordinate legislation made under that Act from time to time together with any guidance or codes of practice issued by any relevant government department in relation to such legislation;

1.11 "**Confidential Information**" shall mean any and all non-public information which by its nature or the manner of its disclosure is reasonably identifiable as confidential information, including but not limited to data, results, know-how, software (further including non-open source code), plans, details of research work, discoveries, inventions, intended publications, intended or pending patent applications, designs, technical information, business plans, budgets and strategies, business or financial information or other information in any medium, and any physical items, prototypes, compounds, samples, components, non-public regulatory filings, non-public submissions to regulatory authorities or other articles or materials disclosed on or after the Effective Date of this Agreement by one Party to the other Party whether orally or in writing or in any other form. Confidential information will not include:

(a) information that is or was already known to the receiving Party at the time of disclosure, as shown by written records, without any obligation to keep it confidential;

(b) information that is independently developed by employees of the receiving Party who have not had access to the Confidential Information of the disclosing Party as evidenced by contemporaneous written records;

(c) information that at the time of being disclosed or obtained by the receiving Party or at any time thereafter, is published or otherwise generally available to the public other than due to default by the receiving Party of its obligations hereunder;

(d) information properly obtained by the receiving Party from a source which, to the best knowledge of the receiving Party, is not known to be bound by a confidentiality agreement, fiduciary obligation or other legal or contractual restriction that may prohibit the disclosure of such Confidential Information;

(e) information necessarily disclosed by the receiving Party pursuant to a statutory obligation and, to the limited extent that it is disclosed for this purpose only, the Party required to make that disclosure has informed the other, within a reasonable time after being required to make such disclosure, of the requirement to disclose and the information required to be disclosed; and

(f) information approved for release in writing by an authorised representative of the disclosing Party.

1.12 **"Continued Storage Option"** shall have the meaning provided in Section 10.1.

1.13 **"Continued Storage Period"** shall have the meaning provided in Section 10.1.

1.14 **"COVAX Approved Partner"** shall mean a third party which is pursuing the development and/or manufacturing of a COVID-19 vaccine without the benefit of CEPI funding and who has been approved by CEPI as a CEPI Partner with a view to procurement funded by the COVAX Facility.

1.15 **"COVAX Facility"** shall mean the financing facility for the procurement of vaccines against COVID-19 disease established by Gavi for the Vaccines Pillar of the ACT-Accelerator established by the World Health Organisation.

1.16 **"Data Protection Regulation"** shall mean the General Data Protection Regulation (GDPR) 2016/679 dated 27 April 2016 and any other EU or Member State legislation, regulation, recommendation or opinion replacing, adding to or amending, extending, reconstituting or consolidating the GDPR

1.17 **"Dynavax Adjuvant"** shall mean Dynavax's proprietary toll-like receptor 9 (TLR9) agonist adjuvant referred to by Dynavax as CpG 1018.

1.18 **"Dynavax CMO"** shall mean the third party contract manufacturer engaged by Dynavax to manufacture Dynavax Adjuvant as of the Effective Date.

1.19 **"Dynavax Material"** shall mean the Dynavax Adjuvant in [***] as described in more detail in **Exhibit A**.

1.20 **"Effective Date"** shall mean the date when the Agreement has been signed by both Parties or, if both Parties signed the Agreement on different dates, the date on which the last Party has signed the Agreement.

1.21 **"Existing CEPI Partner"** shall have the meaning provided in Section 2.4(a).

1.22 **"Extra Capacity"** shall have the meaning provided in Section 2.1(c).

1.23 **"Extra Loan Amount"** shall mean an amount equivalent to the Extra Manufacturing Cost.

1.24 **"Extra Manufacturing Cost"** shall mean the total manufacturing cost of the Extra Reserved Material, based on the manufacturing cost per kilogram cited in the Extra Capacity Notice.

1.25 **"Extra Reserved Material"** shall have the meaning provided in Section 2.1(c).

1.26 **"First Right"** shall have the meaning provided in Section 2.1(c).

1.27 **"First Right Exercise Date"** shall have the meaning provided in Section 2.1(c).

1.28 **"GMP"** shall mean the then-current good manufacturing practices applicable to the manufacture of Dynavax Material under Applicable Laws, including, (a) U.S. 21 C.F.R. Parts 210 and 211 and 21 C.F.R. Parts 600-610, and (b) (i) Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of Medicinal Products for human use and investigational Medicinal Products for human use, (ii) Directive 2001/83/EC laying down the principles and guidelines of good manufacturing practice for Medicinal Products; (iii) further guidance as published by the European Commission in Volume 4 (Good Manufacturing Practice) of "The Rules Governing Medical Products in the European Union" and (iv) ICH Q7 Guideline "Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients."

1.29 **"HICs"** shall have the meaning provided in **Exhibit B** hereto.

1.30 **"Initial Loan Amount"** shall mean an amount equivalent to the total Manufacturing Cost of the Initial Reserved Amount as set forth in Section 3.1(a).

1.31 **"Initial Reserved Material"** shall have the meaning provided in Section 2.1(a).

1.32 **"LMICs"** shall have the meaning provided in **Exhibit B** hereto.

1.33 **"Loan Amount"** shall mean the sum of (a) the Initial Loan Amount, (b) if applicable, the Additional Loan Amount, and (c) if applicable, the Extra Loan Amount.

1.34 **"Loan Drawdown Notice"** shall have the meaning provided in Section 3.1(a).

1.35 **"Manufacturing Cost"** shall have the meaning provided in Section 3.1(a).

1.36 **"Permitted Purchaser"** shall mean a CEPI Partner or Permitted Third Party Purchaser that, in each case, purchases Reserved Material.

1.37 **"Permitted Third Party Purchaser"** shall have the meaning provided in Section 2.5.

1.38 "**Personal Data**" shall mean any subset of data or information that directly or indirectly identifies an individual or that reasonably could identify an individual, including:

(a) Data that directly identifies individuals e.g. name, ID number, national number, social security number, phone number, household address or household GPS coordinates, biological samples, medical imagery, biometrics and all other techniques designed to directly identify individuals.

(b) A combination of data that together can reasonably make it possible to identify an individual.

1.39 **"Project"** shall have the meaning provided in the Recitals.

1.40 **"Quality Agreement"** shall mean the quality agreement between Dynavax and the Dynavax CMO setting out the respective responsibilities of Dynavax and the Dynavax CMO in relation to quality as required for compliance with GMP.

1.41 **"Quarter"** shall mean a period of three calendar months starting on 1 January, 1 April, 1 July and 1 October, respectively in each calendar year. **"Q1"** shall refer to the first Quarter of the calendar year that it refers to, **"Q2"** shall refer to the second Quarter of the calendar year that it refers to, **"Q3"** shall refer to the third Quarter of the calendar year that it refers to, and **"Q4"** shall refer to the fourth Quarter of the calendar year that it refers to. By way of illustration "Q4 2021" refers to the period starting 1 October 2021 and ending 31 December 2021. **"Quarterly"** shall be construed accordingly.

1.42 **"Reimbursement Trigger**" shall mean any of the following: (i) Dynavax's receipt of payment for any Initial Reserved Material, Additional Reserved Material or any Extra Reserved Material from any Permitted Purchaser, or (ii) Dynavax's decision to use the Reserved Material itself in accordance with Section 10.1.

1.43 **"Release Date"** shall mean, with respect to any Reserved Material manufactured pursuant to this Agreement, the date of release of such Reserved Material by Dynavax's quality assurance department.

1.44 **"Reserved Material"** shall mean the Initial Reserved Material and, if applicable, the Additional Reserved Material and the Extra Reserved Material.

1.45 **"Term"** shall have the meaning provided in Section 9.1.

1.46 **"Third Party Committed Capacity"** shall have the meaning provided in Section 2.1(c).

2. Manufacture and Reservation of Dynavax Material

2.1 Manufacture of Dynavax Material.

(a) **Initial Reserved Material.** Subject to the terms and conditions of this Agreement, and in consideration for CEPI advancing the Initial Loan Amount in accordance with Section 3.1(a), Dynavax shall use commercially reasonable efforts to have manufactured [***] kg of Dynavax Material (the **"Initial Reserved Material"**) for release during Q2 2021 and Q3 2021. CEPI's obligation to advance the Initial Loan Amount in accordance with Section 3.1(a) is firm as of the Effective Date and shall not be subject to termination or cancellation.

(b) **Option for Additional Reserved Material.** Subject to the terms and conditions of this Agreement, and in consideration for CEPI advancing the Additional Loan Amount in accordance with Section 3.1(a), CEPI shall have the option (the **"Option"**), exercisable in its sole discretion as set forth below, to require Dynavax to use commercially reasonable efforts to have manufactured an additional [***] kg of Dynavax Material (the **"Additional Reserved Material"**) for release during [***]. CEPI may exercise the Option by delivery of written notice of

exercise to Dynavax no later than [***]. For purposes hereof, **"Option Exercise Date"** means the date on which CEPI delivers (as determined in accordance with Section 13.8) written notice of exercise of the Option to Dynavax. If not exercised by CEPI on or before [***], the Option shall terminate and be of no further force or effect. If CEPI exercises the Option on or before [***], CEPI's obligation to advance the Additional Loan Amount in accordance with Section 3.1(a) shall become firm as of the delivery of such notice of exercise and shall not be subject to termination or cancellation.

(c) First Right to Reserve Extra Dynavax Adjuvant. Subject to the terms and conditions of this Agreement, and in consideration for CEPI advancing the Extra Loan Amount in accordance with Section 3.1(b), Dynavax will use commercially reasonable efforts to reserve extra manufacturing capacity at the Dynavax CMO to manufacture and release up to a further [***]kg of Dynavax Material in 2021. The parties acknowledge that, in addition to the manufacturing capacity necessary to manufacture the Initial Reserved Material and the Additional Reserved Material, as of the Effective Date, Dynavax has reserved manufacturing capacity at the Dynavax CMO necessary to manufacture a total of an additional [***] kg of Dynavax Material for third parties (the **"Third Party Committed Capacity"**), and, accordingly, the parties hereby agree that Dynavax's obligations under this Section 2.1(c) shall only apply to the extent that, either (A) Dynavax identifies extra manufacturing capacity at the Dynavax CMO beyond both (i) the manufacturing capacity necessary to manufacture the Initial Reserved Material and the Additional Reserved Material and (ii) the Third Party Committed Capacity or (B) Third Party Committed Capacity becomes available for other customers (such extra manufacturing capacity under A or B to manufacture and release up to a further [***] kg of Dynavax Material in 2021, **"Extra Capacity"**). If Dynavax identifies Extra Capacity, Dynavax shall promptly notify CEPI thereof, which notice shall specify the number of kilograms of Dynavax Material that the Dynavax CMO will be able to manufacture using such Extra Capacity, the anticipated timing of manufacture and release and the manufacturing cost per kilogram of such Dynavax Material (such notice, the **"Extra Capacity Notice"**). CEPI shall have the first right (the **"First Right"**), exercisable in its sole discretion as set forth below, to require Dynavax to use commercially reasonable efforts to have manufactured the specified additional number of kilograms of Dynavax Material (the **"Extra Reserved Material"**) for release during [***]. CEPI may exercise the First Right by delivery of written notice of exercise to Dynavax within five (5) Business Days after delivery (as determined in accordance with Section 13.8) by Dynavax of the Extra Capacity Notice not to be prior to [***]. For purposes hereof, **"First Right Exercise Date"** means the date on which CEPI delivers (as determined in accordance with Section 13.8) written notice of exercise of the First Right to Dynavax, provided that such delivery is made within such 5-Business Day period. If not exercised by CEPI within five (5) Business Days after delivery of the Extra Capacity Notice, the First Right shall terminate and be of no further force or effect. If CEPI exercises the First Right, CEPI's obligation to advance the Extra Loan Amount in accordance with Section 3.1(b) shall become firm as of the First Right Exercise Date and shall not be subject to termination or cancellation.

(d) Ownership of Reserved Material. Dynavax shall be the sole owner of all Reserved Material manufactured pursuant to this Agreement, and CEPI's only right with respect to any Reserved Material is the right to direct its use in accordance with Sections 2.3 and 2.4.

2.2 Manufacturing Standards. CEPI acknowledges that all Reserved Product will be manufactured on Dynavax's behalf by the Dynavax CMO. Dynavax shall comply, and shall be responsible for ensuring that the Dynavax CMO complies, with all Applicable Laws, including GMP, in carrying out Dynavax's obligations under this Agreement and shall ensure that all necessary approvals are obtained and maintained for the manufacturing facility where the Reserved Materials are manufactured.

2.3 Reservation of Dynavax Material for CEPI Partners. Subject to Section 2.5, Dynavax shall reserve all Reserved Material for purchase by CEPI Partners for use in CEPI Partner Products and shall use it for CEPI Partners in such proportions as CEPI may direct in advance in writing. CEPI may, in its sole discretion, notify Dynavax in writing of one or more COVAX Approved Partners that CEPI desires to designate as "CEPI Partners" under this Agreement at any time. Unless Dynavax notifies CEPI within 15 Business Days of receipt of any such notice with respect to a COVAX Approved Partner that Dynavax is unwilling to supply Dynavax Material to such COVAX Approved Partner for legitimate business reasons (which notice shall set forth the basis for Dynavax's unwillingness), such COVAX Approved Partner shall be deemed a "CEPI Partner" for purposes of this Agreement upon the expiration of such 15-Business Day period. If CEPI wishes to have Dynavax sell and supply Reserved Material to a particular CEPI Partner, CEPI shall deliver written notice to Dynavax of each CEPI Partner to which CEPI wishes to have Dynavax sell and supply Reserved Material, and shall instruct such CEPI Partner to contact Dynavax at [***].

2.4 Disposition of Reserved Material. Dynavax shall use commercially reasonable efforts to sell all of the Reserved Material to Permitted Purchasers in accordance with this Section 2.4 and Sections 2.3 and 2.5. Should a CEPI Partner referred to Dynavax by CEPI pursuant to Section 2.3 contact Dynavax regarding the purchase of Reserved Material for use in CEPI Partner Products, Dynavax shall negotiate in good faith directly with such CEPI Partner a supply agreement on commercially reasonable and customary terms mutually acceptable to Dynavax and such CEPI Partner; *provided, however,* that:

(a) the purchase price(s) per dose of Reserved Material supplied to the existing CEPI Partners identified in **Exhibit B** hereto (**"Existing CEPI Partners"**) shall be as specified in **Exhibit B**;

(b) subject to Section 2.4(c), the purchase price(s) per dose of Reserved Material supplied to any CEPI Partner other than an Existing CEPI Partner shall be determined as follows:

(i) [***]; and

(ii) [***];

(c) notwithstanding Section 2.4(b), in the case of any CEPI Partner (other than an Existing CEPI Partner) with which Dynavax has an effective commercial supply agreement for the Dynavax Adjuvant for such CEPI Partner's CEPI Partner Product as of the date when CEPI delivers written notice to Dynavax that CEPI wishes to have Dynavax sell and supply Reserved Material to such CEPI Partner, the purchase price(s) per dose (regardless of dose size) of Reserved Material supplied to such CEPI Partner shall be the purchase price(s) per dose specified in such commercial supply agreement; and

(d) in each such supply agreement the obligation on Dynavax to ship and supply, as it relates to the Reserved Material, shall be contingent upon CEPI's direction that such portion of the Reserved Material be supplied to such customer.

2.5 Supply of Reserved Material to Permitted Third Party Purchasers. At any time when there are no outstanding firm orders or binding commitments from CEPI Partners for Reserved Material and no supply agreement is then under negotiation between Dynavax and any CEPI Partner, Dynavax may request in writing (which request may be delivered by email to both

of CEPI's nominated contacts specified in Section 13.8) CEPI's consent, which shall not be unreasonably withheld, to the sale and supply by Dynavax to third party(ies) other than CEPI Partners of available Reserved Material. If CEPI fails to respond to any such request for consent within five (5) Business Days of Dynavax's request (which response may be delivered by email to Dynavax's nominated contact specified in Section 13.8), then CEPI shall be deemed to have consented to Dynavax's sale and supply of Reserved Material to such third party(ies). In addition, if any batch of Reserved Material is not subject to firm orders or binding commitments from CEPI Partners for Reserved Material and no supply agreement for Reserved Material is then under negotiation between Dynavax and any CEPI Partner within 90 days after the Release Date for such batch, Dynavax shall have the right to sell such batch of Reserved Material to third parties. Any such permitted sale and supply to a third party other than a CEPI Partner (such third party, a **"Permitted Third Party Purchaser"**) shall be on terms, including purchase price, to be determined by Dynavax in its sole discretion.

2.6 Reporting. On a monthly basis beginning upon the first Release Date for any Initial Reserved Material and until the earlier of (a) such time as all Reserved Material has been sold in accordance with this Agreement (or used by Dynavax as permitted by Section 10.1) or (b) if CEPI exercises the Continued Storage Option, the expiration of the Continued Storage Period, Dynavax shall deliver a report to CEPI within five (5) Business Days after the end of each month setting forth the following information: (i) the total quantity of Reserved Material that has been released by Dynavax from the Effective Date up to the end of such month; (ii) on a Permitted Purchaser-by-Permitted Purchaser basis, the quantity of Reserved Material sold to Permitted Purchasers during such month; and (iii) the total quantity of Reserved Material manufactured and released by Dynavax that remains available for purchase as of the end of such month.

3. FINANCIAL TERMS

3.1 Loan Advance.

(a) Initial Loan Amount and Additional Loan Amount. CEPI shall make available to Dynavax an interest-free, forgivable, unsecured loan for up to a sum equivalent to the manufacturing cost of the Initial Reserved Material, and, if applicable, the Additional Reserved Material (in each case, the **"Manufacturing Cost"**), based on a Manufacturing Cost per kilogram of Dynavax Material of [***], which shall be advanced by CEPI to Dynavax in two installments, upon receipt of a written loan drawdown notice in the form attached hereto as **Exhibit C** (a **"Loan Drawdown Notice"**) for each such installment, as follows:

Quantity	Total Manufacturing Cost	First Installment ([***])	Due Date for First Installment	Second Installment ([***])*	Due Date for Second Installment*
Initial Reserved Material ([***])	[***]	[***]	[***]	[***]	[****]
Additional Reserved Material ([***])	[***]	[***]	[***]	[****]	[****]

* The second installment of the Manufacturing Cost shall be payable on a kilogram-by-kilogram basis, based on [***] of the Manufacturing Cost per kilogram (*i.e.*, [***]), upon the applicable Release Date for a particular quantity of Dynavax Material, written notice of which shall be provided by Dynavax to CEPI.

(b) Extra Loan Amount. If Dynavax identifies Extra Capacity and CEPI exercises its First Right in accordance with Section 2.1(c) above, then effective as of the First Right Exercise Date, CEPI shall make available to Dynavax an interest-free, forgivable, unsecured loan for a sum equivalent to the Extra Manufacturing Cost (the **"Extra Loan Amount"**), which shall be advanced by CEPI to Dynavax in installments, with the first installment equal to [***] of the Extra Manufacturing Cost to be due on the First Right Exercise Date and the second installment equal to [***] of the Extra Manufacturing Cost to be due on the Release Date of the Extra Reserved Material in accordance with the table set forth in Section 3.1(a) (including the note to such table), *mutatis mutandis*, upon receipt of a Loan Drawdown Notice for each such installment.

Loan Drawdown Notices pursuant to Section 3.1(a) and this Section 3.1(b) shall specifically refer to this Agreement and shall be delivered by Dynavax to CEPI via email to [***] fifteen (15) Business Days in advance of the due date except for the first advance which will be made as soon as reasonably practicable after the first Loan Drawdown Notice. The form of the first Loan Drawdown Notice is set out in Exhibit C and the form of subsequent Loan Drawdown Notices shall be agreed in writing between the Parties.

3.2 Reimbursement of Loan Amount. Within 30 days of a Reimbursement Trigger:

(a) in respect of any Initial Reserved Material or Additional Reserved Material, Dynavax shall reimburse to CEPI a portion of the Initial Loan Amount or Additional Loan Amount (as applicable) advanced to Dynavax equal to the Manufacturing Cost for the quantity of Initial Reserved Material or Additional Reserved Material (as applicable) that is the subject of the Reimbursement Trigger;

(b) in respect of any Extra Reserved Material, Dynavax shall reimburse to CEPI a portion of the Extra Loan Amount advanced to Dynavax equal to the Extra Manufacturing Cost for the quantity of Extra Reserved Material that is the subject of the Reimbursement Trigger.

The Parties acknowledge and agree that provided that Dynavax is in material compliance with the material terms of this Agreement, Dynavax shall have no obligation to repay any portion (up to 100%) of the applicable Loan Amount in respect of any Reserved Material that, for any reason, is not subject to a Reimbursement Trigger at the end of the Term and that has been destroyed in accordance with Section 10.1). For clarity, the total amount that Dynavax is obligated to repay to CEPI pursuant to this Section 3.2 shall not exceed the total Loan Amount actually advanced by CEPI to Dynavax pursuant to Section 3.1.

3.3 Manner and Place of Payment. All payments (including repayments) hereunder shall be payable in United States Dollars by wire transfer of immediately available funds to an account designated by the Party entitled to receive payment.

3.4 Late Payments. If any payment due under this Agreement is not paid within 10 Business Days of the due date in accordance with the applicable provisions of this Agreement, such payment shall accrue interest at a rate per annum that is [***] above the then-current prime rate quoted by Citibank in New York City, New York, USA (or such other rate and source as the Parties mutually agree in writing), for the period from the due date for payment until the date of actual payment; *provided, however,* that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

3.5 Failed or Delayed Manufacture of Reserved Material. If Dynavax CMO fails to start manufacture of one or more batches of Reserved Material in time to meet the applicable release date set forth in Section 2.1 or one or more batches of Reserved Material fails to meet its specification for any reason:

(a) Dynavax shall inform CEPI in writing and provide all information known to Dynavax and reasonably necessary for CEPI to make an informed decision, as soon it becomes aware of the same; and

(b) CEPI may in its sole discretion, opt either to (i) accept the delay; (ii) accept Dynavax's manufacture of replacement batch(es) for release within an agreed timeframe which may be after 31 December 2021; or (iii) in a situation where Dynavax has not paid, is not obligated to pay, or has paid but has a contractual right to recover or actually does recover amounts paid, from the Dynavax CMO, reduce the Loan Amount by the portion of the Manufacturing Cost (or Extra Manufacturing Cost, as applicable) for such batch(es), such reduction to be set-off against the next Loan Amount installment or, if CEPI is not obligated to advance any additional Loan Amount to Dynavax, repaid by Dynavax to CEPI within 30 Business Days of a repayment request for the same. For clarity, under no circumstances shall Dynavax have any obligation to pay or repay to CEPI any portion of the Loan Amount advanced to Dynavax that Dynavax has paid or is obligated to pay to the Dynavax CMO and has no contractual right to recover and does not actually recover from the Dynavax CMO.

4. Compliance and Regulatory

4.1 Compliance. Dynavax shall comply with all Applicable Laws, including GMP, and the terms and conditions of this Agreement and the CEPI Third Party Code as described in Section 4.2, in carrying out its obligations under this Agreement and shall ensure that all necessary approvals are obtained and maintained for the manufacturing facility where the Reserved Materials are manufactured (together with the provisions of Section 4.4, the **"Compliance Requirements"**).

4.2 CEPI Third Party Code. The CEPI Third Party Code is a statement of CEPI's values and of the policies, practices and principles applicable to recipients of any funds from CEPI.

(a) Dynavax acknowledges the statement of CEPI's values in Section 1 of the Code.

(b) Dynavax acknowledges CEPI's expectation that Dynavax shall adhere to business practices, ethical principles and legal requirements that are at least substantially similar to those described in Sections 2 to 10 of the Code.

(c) Dynavax shall comply with the requirements for reporting compliance concerns and misconduct to CEPI (Sections 4 and 11 of the Code).

(d) Dynavax shall cooperate as may be requested by CEPI in the submission of information related to Project activities and expenditures in accordance with the International Aid Transparency Initiative (Section 12 of the Code).

(e) Dynavax shall comply with CEPI's Equitable Access Policy.

(f) To the extent applicable to the Project, Dynavax shall comply with CEPI's Animals in Research Policy.

(g) To the extent applicable to the Project, Dynavax may rely upon its own substantially similar policies and principles so as to comply with: (i) CEPI's Clinical Trials Policy; (ii) CEPI's Managing Conflicts of Interest Policy; (iii) CEPI's Scientific Integrity Policy; and (iv) CEPI's Travel and Expenses Policy.

(h) Dynavax shall comply with the provisions related to Sub-Contracts (Section 14 of the Code) and to Sub-Grants (Section 15 of the Code).

4.3 Amendments to the CEPI Third Party Code. CEPI may amend the Third Party Code and/or the CEPI policies incorporated by reference therein from time to time. CEPI shall give Dynavax at least thirty (30) days' written advance notice of such amendments taking effect. If in the reasonable opinion of Dynavax any proposed amendment is likely to have a substantial adverse effect on Dynavax and/or the Project, Dynavax shall promptly notify CEPI. On receipt of such notice, the Parties will discuss and seek to agree in good faith about how to proceed.

4.4 Regulatory. In addition to the other Compliance Requirements:

(a) Dynavax shall manufacture, sample, test and store all Reserved Material in accordance with the Quality Agreement.

(b) On reasonable prior notice, Dynavax shall provide all reasonable co-operation to any inspection by any regulatory authority and shall permit such regulatory authority access to the Dynavax CMO manufacturing site and all relevant records necessary or reasonably desirable in support of the use of the Reserved Material by CEPI Partners as contemplated by this Agreement.

(c) If any regulatory authority notifies the Dynavax CMO or Dynavax of a violation or deficiency in compliance which would impact the use of the Reserved Material by CEPI Partners as contemplated by this Agreement, Dynavax shall share such notification with CEPI within three (3) days of receipt of the same.

5. ANNOUNCEMENTS

5.1 Announcements. Except as required by law or any competent regulatory authority or in compliance with this Article 5, the Parties shall consult on and agree in writing upon the form of all press releases and public announcements concerning this Agreement or its subject matter (**"Announcements"**). Notwithstanding the foregoing, the Parties acknowledge that the existence and general purpose of this Agreement may be disclosed by either Party. For the avoidance of doubt, no Confidential Information introduced by a Party under this Agreement may be published by the other Party without the express prior written consent of the providing Party, and no Personal Data shall be contained in any Announcement and/or other communications to the public. For clarity, nothing in this Agreement shall be construed to prohibit Dynavax from making such press releases, public announcements and other public disclosures concerning this Agreement or its subject matter as are necessary to comply with applicable securities laws, rules and regulations and the requirements of any exchange on which Dynavax's securities are listed.

5.2 Publicity/Use of Name. Neither Party shall use the names, logos or trademarks of the other in any Announcement, advertising, promotion, or for other commercially-related purposes, without the named Party's prior express written consent, except as expressly provided for in this Agreement.

6. Confidentiality and Personal Data

6.1 Confidentiality Obligations. Each Party undertakes that both during the Term and for a period of five (5) years after its termination or expiry, it shall keep confidential and not disclose any Confidential Information of the other Party disclosed to or obtained by it in connection with this Agreement other than its employees, agents, consultants, professional advisers, sub-contractors, regulatory authorities and, in the case of CEPI, CEPI Partners and CEPI's funders, in each case who have a need to know Confidential Information of the other Party and to the extent they are bound by a written agreement or statutory obligation to protect the confidentiality of such Confidential Information equivalent to the provisions contained herein. Each Party shall take reasonable security precautions to protect against unauthorized disclosure of such Confidential Information. Each Party shall use Confidential Information solely in connection with the operation of the Agreement and to the extent that is reasonably necessary for the purposes of the Agreement. Each Party shall ensure that all staff, consultants, agents and third parties to which Confidential Information of the other Party is disclosed are: (i) informed of the confidentiality provisions of this Agreement; and (ii) bound by obligations of confidentiality and non-use at least as protective as the provisions contained herein.

6.2 Required Disclosure. The disclosure of information that is required to be disclosed by a competent court or regulatory authority or otherwise by Applicable Law may be disclosed as required, provided that where it is free to do so, the receiving Party shall give notice of such disclosure to the disclosing Party as soon as reasonably practicable.

6.3 Permitted Disclosures. Notwithstanding the above, nothing in this Agreement shall restrict Dynavax's right to (a) disclose the existence of a relationship between the Parties for the purpose of declaring a potential conflict of interest; or (b) disclose Confidential Information to any committee or regulatory body in furtherance of Dynavax's statutory or regulatory duties. Notwithstanding the above, nothing in this Agreement shall restrict CEPI's right to (a) disclose the existence of a relationship between the Parties for the purpose of declaring a potential conflict of interest; or (b) disclose the nature of the relationship between the Parties, the aggregate Loan Amount and a high level description of how this relationship enables CEPI's mission as it pertains to equitable access to vaccines against SARS-CoV-2.

6.4 Personal Data.

(a) The Parties undertake to comply with Applicable Laws concerning Personal Data, including the Data Protection Regulation.

(b) Except as specifically agreed otherwise in writing among the Parties in order to ensure that medical confidentiality and privacy of patients are fully respected it is hereby acknowledged and agreed that no Personal Data will be shared between the Parties or between Dynavax and CEPI Partners.

(c) Without prejudice to Sections 6.4(b) and 6.4(d), in the event that one Party (the "**Personal Data Supplier**") transfers any Personal Data to another Party (the "**Personal Data Recipient**"), the Recipient undertakes to:

(i) solely process Personal Data in connection with the operation of the Agreement and to the extent that is reasonably necessary for the purposes of the Agreement or otherwise permitted in accordance with Article 28(3)(a) of the GDPR;

(ii) apply appropriate technical and organisational measures so that the processing of Personal Data carried out meets the legal and regulatory requirements in terms of Data Protection Regulation and guarantees the protection of the rights of the persons concerned;

(iii) collaborate with and assist the Personal Data Supplier throughout the processing of Personal Data and alert the Personal Data Supplier to any instructions that appear to be contrary to applicable regulations;

(iv) notify the Personal Data Supplier of any data breach as soon as possible after becoming aware of it, in order to enable the Personal Data Supplier, where appropriate, to fulfil its obligation to notify the data protection supervisory authority and, if necessary, the data subjects;

(v) assist the Personal Data Supplier, within the limits of the information and means made available to it, to respond, within the time limits established by law, to the requests of the persons concerned;

(vi) ensure, in the event of a transfer of Personal Data to a territory outside the European Union, that such transfer complies with applicable law provisions, by signing a separate written agreement;

(vii) inform the Personal Data Supplier of any addition or modification of sub-processors, it being specified that the Personal Data Supplier has ten (10) working days to raise legitimate objections to the sub-processor (an objection based on the sub-processor's non-compliance is considered legitimate);

(viii) return to the Personal Data Supplier or, subject to the Personal Data Supplier prior written instruction, destroy all Personal Data processed on its behalf, unless a legal obligation is imposed on the Recipient, and to confirm such destruction upon request;

(ix) enable the Personal Data Supplier to perform such verifications as it deems necessary, up to a maximum of one (1) audit per year, to ensure that the Recipient complies with the Personal Data Supplier's documented data protection instructions and meets its obligations under this Clause.

(x) It is understood and agreed between the Parties that, if the sharing of Personal Data between the Parties is strictly needed to carry out the Project, a specific additional written data sharing agreement shall be agreed and signed by the Parties before any sharing of Personal Data.

(d) It is understood and agreed between the Parties that, if the sharing of Personal Data between the Parties is strictly needed to carry out the Project, a specific additional written data sharing agreement shall be agreed and signed by the Parties before any sharing of Personal Data.

7. WARRANTIES AND REPRESENTATIONS

7.1 Warranties. As of the Effective Date, each Party warrants to the other Party that it has the full power and authority to enter into and assume all of its obligations under this Agreement. As of the Effective Date, Dynavax warrants to CEPI that the following statements ("**Warranties**") are true and correct:

(a) it has not received any written communication from any third party claiming or alleging that the manufacture, use or sale of the Dynavax Adjuvant infringes, misappropriates or violates the intellectual property, privacy or publicity rights of any third party, and it is not aware of any issued patent of any third party that would be infringed by the manufacture, use or sale of the Dynavax Adjuvant; *provided, however,* that Dynavax makes no warranty or representation whatsoever, and hereby disclaims all warranties and representations, that the manufacture, use or sale of any CEPI Partner Vaccine will not infringe, misappropriate or violate the intellectual property, privacy or publicity rights of any third party; and

(b) none of Dynavax, nor any officer or employee of Dynavax, has been debarred or is subject to debarment by any regulatory authority. Dynavax shall obtain similar written assurances from the Dynavax CMO that neither the Dynavax CMO, nor any officer or employee of the Dynavax CMO, has been debarred or is subject to debarment by any regulatory authority.

7.2 Representations. Dynavax represents that it will comply with the following statements ("**Representations**"):

(a) Dynavax will ensure that its staff exercise reasonable skill and care and at least the level of care, diligence and skill of their profession that other professionals in the same discipline would in the same or similar circumstances in relation to the Project;

(b) Dynavax will ensure that all activities performed by or on behalf of Dynavax under this Agreement have been performed in accordance with all Applicable Laws, including the CEPI Third Party Code where applicable, GMP and the Quality Agreement; and

(c) Dynavax will ensure that no funding received from CEPI pursuant to this Agreement or any Supply Agreement (if applicable) will be directly used to benefit individuals or entities associated with terrorism.

7.3 Continuing Obligation. Dynavax acknowledges a continuing obligation to promptly disclose to CEPI if Dynavax is not in compliance with the foregoing Representations and Warranties or if the Dynavax CMO cannot give similar assurances.

7.4 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, ARE MADE OR GIVEN BY OR ON BEHALF EITHER PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

8. Liability and Indemnity

8.1 Liability cap. Unless otherwise agreed by the Parties in writing, a Party's maximum liability in aggregate to the other Party arising out of this Agreement shall not exceed [***] in respect of breaches other than non-payment of sums owed.

8.2 Exclusions. Neither Party shall be liable to the other Party for any loss of an indirect or consequential nature, nor for any loss of turnover, profits, business or goodwill, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Agreement.

8.3 Exclusions from Liability Cap. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of either Party to the other Party in respect of:

(a) personal injury or death arising out of that Party's negligence or wilful misconduct; or

(b) fraud or fraudulent misrepresentation or wilful misconduct; or

(c) any other liability which cannot be limited or excluded as a matter of Applicable Laws; or

(d) any indemnities under Section 8.4.

8.4 Indemnity. Dynavax shall indemnify CEPI against all liabilities, costs, expenses, damages and losses suffered or incurred by CEPI arising out of:

(a) any claim made against CEPI by a third party for actual or alleged infringement of a third party's intellectual property rights arising out of, or in connection with, the manufacture, supply or use of the Reserved Material, but specifically excluding any claim made against CEPI for actual or alleged infringement of a third party's intellectual property rights arising out of, or in connection with, the manufacture, use or sale of any CEPI Partner Vaccine or CEPI Partner Product except to the extent the basis for such claim is attributable specifically to the Reserved Material contained in such CEPI Partner Product;

(b) any claim made against CEPI by a third party for death, personal injury or damage to property arising out of, or in connection with, defects in the Reserved Material, solely as delivered by Dynavax to a Permitted Purchaser; and

(c) any claim made against CEPI by a third party arising out of or in connection with the supply of the Reserved Material, as delivered by Dynavax to a Permitted Purchaser;

except, in each case, to the extent that such liabilities, costs, expenses, damages and losses result from the breach by CEPI of any representation, warranty, covenant or agreement made by it under this Agreement or the negligence or wilful misconduct of CEPI.

8.5 Mitigating Steps. Each Party shall at all times take all reasonable steps to minimise and mitigate any loss or damage for which the relevant Party is entitled to bring a claim against the other Party pursuant to the indemnities in this Agreement.

8.6 Survival. This Article 8 shall survive termination of the Agreement.

9. Term and Termination

9.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date and shall continue in full force and effect until the earlier of (a) such time as all Reserved Material that Dynavax is obligated to manufacture under this Agreement has been sold in accordance with Section 2.4 or Section 2.5 or disposed of in accordance with Section 10.1 and (b) the second (2nd) anniversary of the Effective Date, and the expiration of this Agreement shall become effective automatically on the earlier of such dates, unless this Agreement is earlier terminated in accordance with this Article 9 or as otherwise agreed to by the Parties in writing.

9.2 Termination of Agreement for Default. Either Party (the "**Terminating Party**") may terminate this Agreement at any time by giving written notice of termination to the other Party (the "**Defaulting Party**"), when:

(a) (i) the Defaulting Party commits a material or persistent breach of this Agreement (which may, without limitation consist of a series of minor breaches) and (ii) the Terminating Party serves a notice on the Defaulting Party requiring the breach to be remedied and if the breach has not been remedied within thirty (30) Business Days of receipt of the notice, or if the breach is not capable of remedy, at the reasonable discretion of the Terminating Party; or

(b) the Defaulting Party becomes insolvent or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of its assets, or if it makes any arrangement with its creditors, or undergoes any similar or equivalent insolvency proceeding anywhere in the world;

it being understood that termination shall become effective automatically upon receipt of written notice of termination, and subject to the above terms in this Section 9.2.

9.3 Termination for Change of Control. CEPI shall have the right to terminate this Agreement with immediate effect in the event that Dynavax experiences a change of Control upon written notice to Dynavax delivered within 30 days after written notice from Dynavax or its acquirer of such change of Control. For purposes of this Agreement, "Control" has the meaning given in section 1124 of the Corporation Tax Act 2010.

10. Effects of Expiration or Termination

10.1 Remaining Reserved Material. CEPI shall have the option (the **"Continued Storage Option"**), exercisable by written notice to Dynavax delivered, as applicable, 10 Business Days prior to expiry of this Agreement or within 10 Business Days after the termination of this Agreement, to require Dynavax to continue to store any Reserved Material that remains unsold and not subject to a binding order by a Permitted Purchaser as of the expiry or termination of this Agreement, for up to an additional twelve (12) months (or such longer period as the parties may mutually agree) from the date of such expiry or termination, if CEPI agrees in writing to reimburse Dynavax for the cost of such storage (which reimbursed costs shall not be considered a loan and shall not be subject to repayment by Dynavax), in which event, during the applicable storage period (the **"Continued Storage Period"**), Sections 2.3, 2.4, 2.5, 2.6 and 3.2 shall survive such expiry or termination as applicable to such Reserved Material. If any Reserved Material remains unsold and not subject to a binding order by a Permitted Purchaser as of (a) unless CEPI exercises the Continued Storage Option, the expiry or termination of this Agreement for any reason or (b) the expiration of the Continued Storage Period, Dynavax shall have the right to sell any such remaining Reserved Material to any third party on terms to be determined by Dynavax and any such third party and/or, on notice to CEPI of the same, to use any such remaining Reserved Material for Dynavax's own products, provided, in each case, that Dynavax shall remain obligated to reimburse CEPI in accordance with Section 3.2 for the Manufacturing Cost actually advanced by CEPI for any such Initial Reserved Material or Additional Material, or the Extra Manufacturing Cost actually advanced by CEPI for any such Extra Reserved Material, as applicable, that Dynavax sells or uses (and Section 3.2 shall survive such expiry or termination of this Agreement for such purpose). If Dynavax does not choose to sell or use any such remaining Reserved Material, it shall destroy it and notify CEPI of the same promptly.

10.2 Return or Destruction of Confidential Information. Upon the expiry or termination of this Agreement for any reason, each Party shall return or destroy the Confidential Information of the other Party disclosed hereunder together with all copies thereof, except each Party may keep one (1) archived copy of such Confidential Information which may be used solely for regulatory purposes and/or for monitoring compliance under this Agreement and shall not be required to delete copies of Confidential Information stored on automatic electronic backup systems.

10.3 Survival of Clauses. Termination or expiry of this Agreement howsoever arising shall be without prejudice to the rights and duties of either Party accrued prior to termination or expiry. The provisions of this Agreement which expressly or by implication are intended to come into or remain in force on or after its termination or expiration shall remain in full force and effect, including Sections 3.2 and 3.4 and Articles 6, 8, 10, 12 and 13, and shall continue to be enforceable notwithstanding termination or expiration.

11. Anti-Corruption and Anti-Bribery

11.1 Neither Party shall:

(a) offer or agree to give any person working for or engaged by the other Party any gift or other consideration which could act as an inducement or a reward for any act or failure to act connected to this Agreement, or any other agreement between the Parties; nor

(b) enter into this Agreement if it has knowledge that, in connection with this Agreement, any money has been, or will be, paid by or for itself to any person working for or engaged by the other Party, or that an agreement has been reached to that effect, unless details of any such arrangement have been disclosed in writing to the other Party before execution of this Agreement.

11.2 Without prejudice to Section 11.1:

(a) Dynavax acknowledges that:

(i) CEPI has to comply with the BA and the CFA and all other Applicable Laws, regulations, codes and sanctions relating to anti-bribery and anti-corruption; and

(ii) CEPI has to maintain in place adequate procedures (as referred to in section 7(2) of the BA and any guidance issued by the Secretary of State under Section 9 of the BA) designed to prevent any associated person from undertaking any conduct that would give rise to an offence under section 7 of the BA;

(b) In order to allow CEPI to comply with its statutory obligations under Section 11.2(a)(i), Dynavax agrees that it shall comply with all of CEPI's ethics, anti-bribery and anti-corruption policies at all times;

(c) Dynavax shall promptly report to CEPI any request or demand for any undue financial or other advantage of any kind received by Dynavax in connection with the performance of this Agreement;

(d) Dynavax shall not engage in any activity, practice or conduct which would constitute either:

(i) a tax evasion facilitation offence within the meaning of section 45(1) of the CFA; or

(ii) a foreign tax evasion facilitation offence within the meaning of section 46(1) of the CFA;

(e) Dynavax shall promptly report to CEPI any request or demand from a third party to facilitate the evasion of tax within the meaning of Part 3 of the CFA or any suspected tax evasion offences or facilitation of tax evasion offences, whether under UK law or under the law of any foreign country, in connection with the performance of this Agreement;

(f) Dynavax shall ensure that all employees and officers of Dynavax, and shall use all reasonable endeavours to ensure that all other persons who are performing services on behalf of Dynavax in connection with this Agreement, comply with this Article 11; and

(g) Dynavax shall provide such supporting evidence of compliance with this Article 11 as CEPI may reasonably request.

11.3 If Dynavax becomes aware of any breach or suspected breach by CEPI (or by anyone employed by it or acting on its behalf) of Section 11.1 or 11.2, Dynavax must notify CEPI immediately and must respond promptly to CEPI's enquiries and co-operate with any investigation.

11.4 Any breach of this Article 11 by either Party or by anyone employed by it or acting on its behalf shall entitle the other Party to terminate this Agreement forthwith.

12. Dispute Resolution, Jurisdiction and Governing Law

12.1 Escalation process. Any claim, controversy, difference, dispute, proceedings or question ("**Dispute**") which may arise concerning the construction, meaning or effect of this Agreement, or concerning the rights or liabilities of the Parties hereunder, or any other matter arising out of or in connection with this Agreement will first be submitted to the Chief Executive Officer or designee of the Parties (the "**Senior Officers**") for resolution (each of whom may call on others to advise them as they see fit) unless this Agreement expressly provides otherwise. The Senior Officers shall discuss the Dispute in good faith and in a timely manner and endeavour to reach a mutually agreeable solution. If the Senior Officers are unable to resolve such Dispute within sixty (60) days from submission of the Dispute to the Senior Officers, then in respect of any dispute, the Parties irrevocably submit to the exclusive jurisdiction of the courts of England and Wales.

12.2 Governing Law. Subject to Section 12.1, this Agreement and any Dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the substantive laws of England without reference to the choice of law rules.

13. General

13.1 Waiver. Neither Party shall be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorized representative of that Party.

13.2 Entire Agreement. The Parties agree that this Agreement, including its Exhibits, constitutes the entire agreement and understanding between the Parties relating to its subject matter and together they supersede and replace all prior drafts, previous understandings, arrangements, representations or agreements, whether in writing or oral, between the Parties relating to the subject matter of this Agreement.

13.3 Variation. No variation, amendment, modification or supplement to this Agreement shall be valid unless and until it is made in writing and signed by a duly authorised representative of each Party.

13.4 Assignment. Neither Party shall, without the prior written consent of the other Party assign, transfer, convey or declare a trust over this Agreement or make any other disposition (whether in whole or in part) of any of its rights and obligations hereunder to any Third Party, including by novation; EXCEPT THAT CEPI may, following written notification to Dynavax transfer its rights and obligations to an organisation of equivalent charitable mission, if CEPI considers (in good faith) that CEPI will not be in a position to fulfil its obligations or exercise its rights in the future.

13.5 Severance of Terms. If the whole or any part of this Agreement is or becomes or is declared illegal, invalid or unenforceable in any jurisdiction for any reason:

(a) in the case of the illegality, invalidity or un-enforceability of the whole of this Agreement it shall terminate only in relation to the jurisdiction in question; and

(b) in the case of the illegality, invalidity or un-enforceability of part of this Agreement that part shall be severed from this Agreement in the jurisdiction in question and that illegality, invalidity or un-enforceability shall not in any way whatsoever prejudice or affect the remaining parts of this Agreement, which shall continue in full force and effect.

13.6 Costs. Each Party shall bear its own legal costs, legal fees and other expenses incurred in the preparation, negotiation and execution of this Agreement.

13.7 Further Assurances. Each Party shall perform such acts and execute such documents as reasonably may be required for securing to or vesting in the other Party the rights agreed to be granted to it pursuant to this Agreement.

13.8 Notices. Any notice to be given pursuant to this Agreement shall be in writing in the English language to the address of the recipient Party set forth below in this Section 13.8 or such other address as a Party may from time to time designate by written notice to the other Party for the attention of the recipient's nominated contact specified below and, except as expressly set forth below, shall be delivered:

(a) personally, in which case the notice will be deemed to have been received at the time of delivery;

(b) by pre-paid, first-class post if the notice is being sent to an address within the country of posting, in which case the notice will be deemed to have been received at 09:00 in the country of receipt on the second (2nd) Business Day in the country specified in the recipient's address for notices after the date of posting; or

(c) by international standard post if being sent to an address outside the country of posting, in which case the notice will be deemed to have been received at 09:00 in the country of receipt on the seventh (7th) Business Day in the country specified in the recipient's address for notices after the date of posting. To prove service of notice, it is sufficient to prove that the envelope containing the notice was properly addressed and posted or handed to the courier.

Dynavax address for notice:	**CEPI addresses for notice:**
[***]	[***]

The Parties agree that email is a valid method of giving notice under this Agreement with acknowledgement of receipt or delivery. Any notice or other communication delivered by email as permitted by the preceding sentence will be deemed to have been received on the first (1st) Business Day in the country specified in the recipient's address for notices after the date of transmission of such email.

13.9 Partnership. Nothing in this Agreement (notwithstanding the use of the defined term "CEPI Partner") shall be taken to constitute a partnership between the Parties. Except as specifically provided in this Agreement, neither Party shall by reason of this Agreement be empowered to act as agent for the other Party nor to pledge the credit of the other Party nor shall either Party be held liable for or incur liability in respect of the acts or defaults of the other Party to this Agreement.

13.10 Counterparts. This Agreement may be executed in counterparts, including electronic counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute one and the same instrument.

13.11 Rights of Third Parties. A person who is not a Party has no right under any relevant law or legislation including the Contracts (Rights of Third Parties) Act 1999 to enforce or to enjoy the benefit of any term of this Agreement.

13.12 Force Majeure. Neither Party shall be deemed to have defaulted under or to be in breach of this Agreement for failure or delay in fulfilling material obligations when such failure or delay is directly caused by an event outside of their reasonable control, including but not limited to war, acts of war, insurrections, acts of terrorism, epidemics or pandemics, acts of God, or acts, omissions or delays in acting or failure to act by any of CEPI's funders provided this is not due to a breach of an obligation or any undertaking of CEPI owed to CEPI's funders (collectively a "**Force Majeure Event**"). Each Party shall inform the other promptly and in writing of such Force Majeure Event and the Parties will discuss the situation, and acting in good faith, agree on the appropriate course of action under the circumstances.

13.13 Taxation. All amounts payable by CEPI under this Agreement are exclusive of amounts in respect of any applicable valued added tax (or national equivalent), any applicable sales tax, export or import duty or any other taxes (other than VAT and taxes imposed on the profits of an entity), currency exchange expenses or banking charges under any Applicable Laws (**"Applicable Tax Amount"**), and CEPI shall be liable to pay such Applicable Tax Amount. Should CEPI be required to account for VAT by reverse charge, then such reverse charge is accounted for on top of the agreed payment amount and shall not be withheld from the agreed payment amount.

[*Signature page follows.*]

In Witness Whereof, the Parties hereto have caused this Agreement to be executed and entered into by their duly authorized representatives as of the date(s) specified below.

Signed for and on behalf of **COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS** by:

Signature:…/s/ Dr. Richard Hatchett ……

Name: Dr. Richard Hatchett

Title: Chief Executive Officer

Date:……January 29, 2021…….

Signed for and on behalf of **DYNAVAX TECHNOLOGIES CORPORATION** by:

Signature:… /s/ Ryan Spencer ……

Name: Ryan Spencer

Title: Chief Executive Officer

Date:…January 28, 2021…….

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

Exhibit A

Dynavax Material

[***] of Dynavax Adjuvant in [***]L containers (filled to approximately [***]L), at a concentration of [***] mg/ml, provided that, for each full batch of Dynavax Material manufactured, the last container filled will contain the remaining volume from such batch, which may be less than [***]L.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

Exhibit B

Pricing for Existing CEPI Partners

Existing CEPI Partner	Size of Dose of Dynavax Adjuvant	Pricing (in United States Dollars)
[***]	[***] milligrams, net of any overage	**LMIC Price.** For Reserved Material for use in CEPI Partner Product for sale or distribution in countries supported by the Advance Market Commitment of the COVAX Facility as listed at the following website: https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc ("**LMICs**"): •USD [***] per dose of Reserved Material for total combined calendar year orders of Reserved Material between [***] and [***] doses •USD [***] per dose of Reserved Material for total combined calendar year orders of Reserved Material between [***] and [***] doses •USD [***] per dose per dose of Reserved Material if total combined calendar year orders of Reserved Material exceed [***] doses **HIC Price.** For Reserved Material for use in CEPI Partner Product for sale or distribution in countries that are not LMICs ("**HICs**"): •USD [***] per dose of Reserved Material For clarity, the pricing set forth above applies *solely* to Reserved Material supplied and sold to [***]. The pricing of any Dynavax Material, other than Reserved Material, supplied and sold by Dynavax to [***] shall be mutually agreed by Dynavax and [***] without regard to this Agreement.
[***]	[***] milligrams, including overage	**LMIC Price.** For Reserved Material for use in CEPI Partner Product for sale or distribution in LMICs: •USD [***] per dose of Reserved Material **HIC Price.** For Reserved Material for use in CEPI Partner Product for sale or distribution in HICs: •USD [***] per dose of Reserved Material For clarity, the pricing set forth above applies *solely* to Reserved Material supplied and sold to [***]. The pricing of any Dynavax Material, other than Reserved Material, supplied and sold by Dynavax to [***] shall be mutually agreed by Dynavax and [***] without regard to this Agreement.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

EXHIBIT C

Loan Drawdown Notice

Awardee name	
Address	
Reg.no.	
Subject:	**Loan payment request**
Your reference	
CEPI's reference	[***]
Vaccine candidate	COVID-19
Loan request number	
Please specify the purpose of this payment request	
Total loan requested	**$-**

CEPI New vaccines for a safer world

Coalition for Epidemic Preparedness Innovations, CEPI
Marcus Thranes gate 2
0473 OSLO
Norway
Registration number: 917687811

Expected Repayment Date (utilization)	
Price per kilogram	[***]
Quantity ordered	kg

Awardee Bank Account Details for Receipt of CEPI Loan Funds

Account holder	
Name of bank	
Branch address	
IBAN	
BIC/SWIFT	

I hereby confirm that the Representations and Warranties in the Agreement remain true, complete and accurate; and

I hereby declare that to the best of my knowledge all information provided in this payment request is full, reliable and true.

Place and date

Signature authorised representative

Printed name and title

Exhibit 10.32

AMENDMENT NO. 4 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 4 TO TERM LOAN AGREEMENT, dated as of January 28, 2021 (this "***Agreement***"), is made among Dynavax Technologies Corporation, a Delaware corporation (the "***Borrower***"), the Subsidiary Guarantors party hereto, the Lenders party hereto and CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, "***Agent***"), with respect to the Loan Agreement referred to below.

RECITALS

WHEREAS, the Borrower, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and the Agent are parties to that certain Term Loan Agreement, dated as of February 20, 2018, as amended by that certain Waiver and Amendment, dated as of November 20, 2018, that certain Amendment No. 2 to Term Loan Agreement and Fee Letter, dated as of August 7, 2019 and effective as of August 7, 2019, that certain Consent, dated as of April 21, 2020, that certain Consent, dated as of July 31, 2020 and that certain Amendment No. 3 to Term Loan Agreement, dated as of November 2, 2020 (as further amended, amended and restated, modified or otherwise supplemented from time to time, the "***Loan Agreement***"); and

WHEREAS, the parties hereto desire to amend the Loan Agreement on the terms and subject to the conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Agreement (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.03 of the Loan Agreement shall be applicable to this Agreement and are incorporated herein by this reference.

SECTION 2. Amendments. Subject to **Section 3**, the Loan Agreement is hereby amended as follows:

(a) Section 1.01 of the Term Loan Agreement is hereby amended by inserting the following new definitions in the appropriate alphabetical order:

"***CEPI***" means the Coalition for Epidemic Preparedness Innovations.

"***CEPI Agreement***" means that certain Agreement dated as of January 28, 2021 between CEPI and the Borrower, as amended, modified, extended, restated, replaced or supplemented from time to time in accordance with the terms and provisions of this Agreement.

"***Fourth Amendment Effective Date***" means January 28, 2021.

(b) Section 9.01 of the Loan Agreement is hereby amended by (i) replacing the text "; and" at the end of clause (u) thereof with the text ";", (ii) replacing the text "." at the end of clause (v) thereof with the text "; and" and (iii) adding the following as a new clause (w) thereof to read as follows:

(w) unsecured Indebtedness owing by the Borrower to CEPI pursuant to the CEPI Agreement in an aggregate principal amount at any time outstanding not to exceed the "Loan Amount" as defined in the CEPI Agreement (as in effect on the Fourth Amendment Effective Date).

(c) Section 9.07 of the Loan Agreement is hereby amended by (i) replacing the text ", and (v)" with the text ", (v)" and (ii) replacing the text "." at the end of such section with the following text:

and (vi) payments of Indebtedness outstanding under **Section 9.01(w)** as required under Section 3.2 or 3.5(b) of the CEPI Agreement (as in effect on the Fourth Amendment Effective Date).

(d) Pursuant to Section 7.20 of the Loan Agreement, the CEPI Agreement is hereby added to Schedule 7.14 of the Disclosure Letter and shall be deemed to be a "Material Agreement" for all purposes of the Loan Agreement and the other Loan Documents.

SECTION 3. Conditions to Effectiveness. The effectiveness of **Section 2** shall be subject to the satisfaction of each of the following conditions precedent:

(a) Agent shall have received, in form and substance reasonably satisfactory to it and Lenders, counterparts of this Agreement duly executed by Borrower, Agent and the Majority Lenders.

(b) The representations and warranties in **Section 5** shall be true in all material respects on the date hereof and on the date on which the foregoing condition is satisfied.

SECTION 4. Expenses. The Obligors agree to reimburse the Agent for all reasonable fees, charges and disbursements of the Agent in connection with the preparation, execution and delivery of this Agreement, including the reasonable fees, charges and disbursements of Moore & Van Allen PLLC.

SECTION 5. Representations and Warranties. Each Obligor hereby represents and warrants to Agent and each Lender as follows:

(a) Such Obligor has full power, authority and legal right to make and perform this Agreement and the Loan Agreement, as modified by this Agreement (the "***Amended Loan Agreement***"). Each of this Agreement and the Amended Loan Agreement is within such Obligor's corporate or equivalent powers and has been duly authorized by all

necessary corporate or equivalent action and, if required, by all necessary shareholder action. This Agreement has been duly executed and delivered by such Obligor and each of this Agreement and the Amended Loan Agreement constitutes legal, valid and binding obligations of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). Each of this Agreement and the Amended Loan Agreement (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate any applicable law or regulation or the charter, bylaws or other organizational documents of such Obligor and its Subsidiaries or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, and (z) will not violate or result in an event of default under any material indenture, agreement or other instrument binding upon any Obligor or any of its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person.

(b) No Default has occurred and is continuing or will result after giving effect to this Agreement.

(c) There has been no Material Adverse Effect since the date of the Loan Agreement.

(d) The representations and warranties made by or with respect to such Obligor in Section 7 of the Loan Agreement are true in all material respects (and, in all respects, for such representations and warranties that are by their terms already qualified as to materiality, material adverse effect or similar language), taking into account any changes made to schedules updated in accordance with Section 7.20 of the Loan Agreement, except that such representations and warranties that refer to a specific earlier date were true in all material respects on such earlier date (and, in all respects, for such representations and warranties that are by their terms already qualified as to materiality, material adverse effect or similar language).

SECTION 6. Reaffirmation. Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Agreement, except as expressly provided herein. By executing this Agreement, each Obligor acknowledges that it has read, consulted with its attorneys regarding, and understands, this Agreement.

SECTION 7. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) **Governing Law**. This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in

the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Each Obligor agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the nonexclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 7** is for the benefit of Lenders and the Agent only and, as a result, neither the Agent nor any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Agent and Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **Waiver of Jury Trial**. EACH OBLIGOR, THE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

SECTION 8. No Actions, Claims, Etc. Each Obligor acknowledges and confirms that it has no knowledge of any actions, causes of action, claims, demands, damages or liabilities of whatever kind or nature, in law or in equity, against any Secured Party, in any case, arising from any action or failure of any Secured Party to act under any Loan Document on or prior to the date hereof, or of any offset right, counterclaim or defense of any kind against any of its respective obligations, indebtedness or liabilities to Secured Party under any Loan Document. Each Obligor unconditionally releases, waives and forever discharges (a) any and all liabilities, obligations, duties, promises or indebtedness of any kind of Agent or any Lender to such Obligor, except the obligations required to be performed by Agent or any Lender under the Loan Documents on or after the date hereof, and (b) all claims, offsets, causes of action, suits or defenses of any kind whatsoever (if any), whether arising at law or in equity, whether known or unknown, which such Obligor might otherwise have against any Secured Party in connection with the Loan Documents or the transactions contemplated thereby, in the case of each of **clauses (a)** and **(b)**, on account of any past or presently existing condition, act, omission, event, contract, liability, obligation, indebtedness, claim, cause of action, defense, circumstance or matter of any kind. Each Obligor acknowledges that it may discover facts or law different from, or in addition to, the facts or law that it knows or believes to be true with respect to the claims released in this **Section 8** and agrees, nonetheless, that this release shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them. Each Obligor expressly acknowledges and agrees that all rights under Section 1542 of the California Civil Code are expressly waived. That section provides:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF

KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR."

SECTION 9. Miscellaneous.

(a) **No Waiver**. Nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Agent and Lenders reserve all rights, privileges and remedies under the Loan Documents (including, without limitation, all such rights, privileges and remedies with respect to any Default, Event of Default or Material Adverse Effect, whether or not communicated to Lenders or Agent). Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as modified hereby.

(b) **Severability**. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Agreement (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Agreement constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart. Receipt by facsimile or other electronic transmission of any executed signature page to this Agreement shall constitute delivery of such signature page.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Agreement and the provisions of any other Loan Document, the provisions of this Agreement shall govern and prevail.

(g) **Loan Document**. This Agreement is a Loan Document.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the day and year first above written.

BORROWER:

DYNAVAX TECHNOLOGIES CORPORATION
By: /s/ RYAN SPENCER
Name: Ryan Spencer
Title: Chief Executive Officer

[Signature Page to Amendment No. 4]

AGENT:

CRG SERVICING LLC

By: /s/ NATHAN HUKILL
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG ISSUER 2017-1

By: CRG SERVICING LLC,
acting by power of attorney

By: /s/ NATHAN HUKIL
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV 1 L.P.

By: CRG PARTNERS III (CAYMAN) GP L.P.,
its General Partner

By: CRG PARTNERS III GP LLC,
its General Partner

By: /s/ NATHAN HUKIL
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ NICOLE NESSON
Name: Nicole Nesson

CRG PARTNERS III-PARALLEL FUND "A" L.P.

By: CRG PARTNERS III-PARALLEL FUND "A" GP L.P.,
its General Partner

By: CRG PARTNERS III GP LLC,
its General Partner

By: /s/ NATHAN HUKIL
Name: Nathan Hukill
Title: Authorized Signatory

[Signature Page to Amendment No. 4]

December 14, 2020

Kelly MacDonald

Subject: Offer Letter

Dear Kelly:

Dynavax Technologies is pleased to offer you the position of Senior Vice President, Chief Financial Officer**,** on the terms outlined below. We are excited that you will be joining our team of dedicated and talented professionals focused on investigating, developing and commercializing innovative vaccines to provide protection for an unpredictable world.

As our CFO, you will report to Ryan Spencer, CEO, and work at our facility located at 2100 Powell Street, Suite 900 in Emeryville, California. The Company may change your position, duties, manager, and work location from time to time as it deems necessary.

Our offer of employment is contingent upon your appointment as CFO by the Dynavax Board of Directors.

COMPENSATION & BENEFITS

Your compensation will be $31,250.00 per month, annualized to $375,000.00, less payroll deductions and all required withholdings. You will be paid semi-monthly on the 15th of each month and on the last day of each month. You will be eligible to participate in the Company's standard benefit programs including medical, dental, and vision insurance programs for yourself and your qualified dependents beginning on your first day of employment. There will be an employee contribution for these coverages. Dynavax offers up to 13 company paid holidays per year, life insurance, disability insurance, long-term care insurance, Flexible Spending Account, 401(k) match, and Employee Stock Purchase Plan. The Company may modify compensation and benefits from time to time as it deems necessary.

As a Director and above level employee, you will be eligible for our "Non-accrual Vacation Policy for Director & Above Employees". A copy of the policy will be sent to you under separate cover.

BONUS

You are eligible to participate in the Company's Bonus Plan with a target incentive of 50% of your annual base salary. Your annual cash incentive is 20% based on your individual performance and 80% of the corporate goals. Payment of the Company's Bonus Plan is determined based on your individual performance (including the accomplishment of individual goals) and the Company's accomplishment of approved corporate goals. The payout of the Company's Bonus Plan is at the discretion of the Dynavax Board of Directors. Employees who join the company between January 1st and on the first business day in October of such performance year, will be eligible for prorated annual compensation awards (bonus, merit, and annual equity grant) for their first year of employment. Employees hired after the first business day in October will be eligible to participate in our annual compensation awards the following year.

STOCK OPTIONS

The Company will grant you a stock option to purchase 350,000 shares of the Common Stock of the Company, with an exercise price equal to the closing price of the Common Stock on the date your first day of employment with Dynavax. Your new hire equity grant will be comprised of NQ stock options issued from our inducement pool. This stock option is subject to all of the terms and conditions set forth in the applicable award agreement and applicable stock incentive plan. Your stock option grant of 350,000 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.

SIGN-ON BONUS

You will receive a $15,000 sign-on bonus, less applicable withholding deductions that will be paid in the pay cycle after completing 30-days of full-time employment. If you voluntarily terminate your employment within 12-months of your start date, this amount must be reimbursed to the Company.

RELOCATION BENEFITS

Your relocation package will be paid by Dynavax and will include the following benefits:

- Pack and move usual and customary household goods from Boston, MA to your residence in San Francisco, CA.
- Ship and un-pack stored household goods at your residence in San Francisco, CA.
- Move up to two automobiles from Boston, MA to San Francisco, CA.
- One-way trip to relocate you and your immediate family including your pet(s) to San Francisco, CA.
    - Economy Plus Class (or equivalent class) airfare arranged through Dynavax's travel agent in accordance with the company's travel and expense policy.

If you voluntarily terminate your employment within 12-months of your start date, you must reimburse Dynavax for all relocation expenses that Dynavax paid for or reimbursed you for in connection with your relocation.

The relocation benefits eligible under the IRS will be grossed up to cover appropriate withholding deductions.

OTHER AGREEMENTS

As a Senior Vice President, you will receive our Management Continuity and Severance Agreement (MCSA) at the benefit levels as approved by the Compensation Committee and defined in the agreement. In addition, you will receive our standard Indemnity Agreement. Copies of these agreements will be delivered to you as soon as administratively possible after your first day of employment.

EMPLOYMENT VERIFICATION & BACKGROUND CHECK

This offer is subject to your submission of a completed and signed I-9 form within 3 days of your employment, along with satisfactory documentation(s) verifying your identification and right to work in the United States.

Your employment is also contingent upon the acceptable results of reference checks, and background checks, including but not limited to your Social Security number, education, employment, FACIS (Fraud and Abuse Control Information System), credit check, and criminal verification (including the 50-state sex offender database). Any falsification in your employment history, educational and criminal background will result in withdrawal of the offer, or termination of employment, if hired.

COMPANY POLICY & PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT
As an employee of the Company, you will be expected to abide by Company rules and regulations as well as the Dynavax Code of Business Conduct and Ethics, and to sign and comply with a Proprietary Information and Inventions Agreement, which prohibits unauthorized use or disclosure of the Company's proprietary information.

WORKING HOURS
Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt salaried employee, you will be expected to work additional hours as required by the nature of your work assignments.

AT-WILL EMPLOYMENT
You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason whatsoever, with or without cause or advanced notice. This at-will employment relationship cannot be changed except by written agreement signed by a Company officer.

The employment terms in this letter and your Management Continuity and Severance Agreement (MCSA) supersede any other agreements or promises made to you by anyone, whether oral or written.

Please sign and date this letter and return it via DocuSign to Human Resources by **Friday, December 18, 2020**, if you wish to accept employment with Dynavax under the terms described above. If you accept our offer, we would like you to start no later than **March 1, 2021**.

Kelly, we look forward to a favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ RYAN SPENCER

Ryan Spencer
CEO

Accepted:

/s/ KELLY MACDONALD	12/15/2020
Kelly MacDonald	Date

Exhibit 21.1

List of Subsidiaries

Dynavax GmbH

Dynavax India LLP

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. 333-239663 and 333-241678) 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, 333-233247 and 333-241674) pertaining to the Amended and Restated 2011 Equity Incentive Plan, the Amended and Restated 2014 Employee Stock Purchase Plan, the 2017 Inducement Award Plan, the 2018 Equity Incentive Plan and Amended and Restated 2018 Equity Incentive Plan of Dynavax Technologies Corporation;

of our reports dated February 25, 2021, 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, 2020.

/s/ Ernst & Young LLP

San Francisco, California
February 25, 2021

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: February 25, 2021

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: February 25, 2021

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, 2020, 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 25th day of February, 2021.

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, 2020, 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 25th day of February, 2021.

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.