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, 2021

☐ **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, 2021 as reported on the Nasdaq Capital Market, was approximately $1.0 billion. 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 24, 2022, the registrant had outstanding 124,921,757 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2022 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, 2021.

Auditor Firm Id: 42 Auditor Name: Ernst & Young LLP Auditor Location: San Francisco, California

INDEX

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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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, CpG 1018 adjuvant or any future product, our anticipated market opportunity and level of sales of HEPLISAV-B and CpG 1018 adjuvant, 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 CpG 1018 adjuvant, including any current or potential vaccine for COVID-19 that stem from any collaborations, 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, our ability to develop and expand our clinical research pipeline, our ability 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 for our business. These statements appear throughout this Annual Report on Form 10-K 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 words of similar import. 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 Annual Report on 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 Annual Report on Form 10-K. 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 these marketplaces. 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. We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop vaccines 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 adjuvant or otherwise are inadequate, we may be unable to realize recurring commercial benefit from the development of any vaccines containing CpG 1018 adjuvant.
- Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.
- We face uncertainty regarding coverage, pricing and reimbursement and the practices of third-party payors, which may make it difficult or impossible to sell certain of our products or product candidates on commercially reasonable terms.
- We are subject to ongoing United States Food and Drug Administration (“FDA”) and European Medicines Agency (“EMA”) 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 regulatory issues 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.
- Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Conversion of our Convertible Notes (defined below) may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.
- Despite recent profitability, we have incurred annual net losses in each year since our inception and anticipate that we could continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and/or continue to sell significant quantities of our CpG 1018 adjuvant, and if we are unable to 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 on a consistent basis, we may 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. or Europe, 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 products or 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 may have uncertain outcomes.
- 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 revenue from such product candidates.
- HEPLISAV-B and most of our earlier stage programs, including our CpG 1018 adjuvant, rely on oligonucleotide toll-like receptor (“TLR”) agonists. In the event of any serious adverse event data relating to TLR agonists, we may be required 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 our CpG 1018 adjuvant, 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 Düsseldorf, Germany, and our existing suppliers for CpG 1018 adjuvant, 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 approved or potential vaccine utilizing CpG 1018. There can be no assurance that we, our existing suppliers, 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 and our collaborators have limited experience in manufacturing our products and product candidates in commercial quantities. With respect to HEPLISAV-B, we use a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our or our contract manufacturer's ability to provide sufficient supply in this presentation.
- As we continue to grow as a commercial organization and enter into supply agreements with customers and collaborators, 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 or manage 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. These relationships may not succeed on expected timelines, or at all.
- 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.
- 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.
- 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

Our Company

We are a commercial stage biopharmaceutical company dedicated to developing and commercializing innovative vaccines in areas of significant unmet need, leveraging our demonstrated expertise and capabilities in vaccines and our proven vaccine adjuvant technology. We are currently focused on our efforts to drive long-term shareholder value by maximizing utilization of our HEPLISAV-B® hepatitis B vaccine, advancing our CpG 1018® adjuvant supply strategy, most notably through COVID-19 collaborations, and expanding our portfolio of innovative vaccine candidates leveraging our proven adjuvant technology.

Our first marketed product, HEPLISAV-B (Hepatitis B Vaccine (Recombinant), Adjuvanted), is approved in the United States and European Union for prevention of infection caused by all known subtypes of hepatitis B virus ("HBV") in adults age 18 years and older. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S. and European Union. 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 for prevention of infection caused by all known subtypes of HBV in adults age 18 years and older. In May 2021, we entered into a commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany and we expect to begin distribution in 2022.

We also manufacture and sell CpG 1018 adjuvant, the vaccine adjuvant used in HEPLISAV-B. We developed CpG 1018 adjuvant to provide an increased vaccine immune response, which has been demonstrated in real world commercial use and in a wide range of clinical trials. We are expanding the use of our adjuvant to support the development and potential large-scale manufacturing of additional vaccines through collaborations with multiple vaccine companies, academic groups and in our own vaccine development programs. Current adjuvant supply collaborations primarily include a diverse, global portfolio of COVID-19 vaccine developers.

We expect to drive future innovation through our clinical pipeline and discovery efforts. Currently, we have three clinical development programs, and additional pre-clinical and clinical collaborations:

- Our tetanus, diphtheria, and acellular pertussis (“Tdap”) booster vaccine candidate, adjuvanted with CpG 1018, is in a Phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity of the vaccine, with topline data for adults expected in the first half of 2022, and topline data for adolescents expected in the second half of 2022.
- Our investigational shingles vaccine candidate, adjuvanted with CpG 1018, is currently in a Phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity of the vaccine, with topline data expected by the end of 2022.
- In collaboration with, and fully funded by, the U.S. Department of Defense, we plan to conduct a phase 2 clinical trial for a plague vaccine adjuvanted with CpG 1018, which is anticipated to begin in the second half of 2022.
- We are also working to advance product candidates utilizing our CpG 1018 adjuvant through pre-clinical and clinical collaborations and additional discovery efforts with third-party research organizations, including an ongoing collaboration with the Icahn School of Medicine at Mount Sinai ("Mount Sinai"), investigating universal and seasonal influenza vaccine candidates.

Adjuvant Technology Overview: 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. Compounds that stimulate enhanced immune responses are generally referred to as adjuvants.

Our work in this area 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 unmethlyated synthetic

oligonucleotides (short segments of deoxyribonucleic acid (“DNA”)), that mimic the activity of microbial DNA, and selectively activate one of these important receptors, TLR9. These TLR9 agonists are called CpG oligonucleotides – or “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 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 more durable levels of protective antibodies relative to non-adjuvanted vaccines. Our CpG 1018 adjuvant has an established tolerability profile demonstrated in a wide range of clinical trials and real-world, commercial use, and has consistently demonstrated its ability to enhance the immune response without excessive reactogenicity in HEPLISAV-B and multiple COVID-19 clinical trials.

Key 2021 Highlights and Performance Against Core Priorities

Maximize Growth of HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted]

- We recognized approximately $61.9 million in product revenue related to sales of HEPLISAV-B in the U.S. during the year ended December 31, 2021, representing a 72% increase compared to the year ended December 31, 2020. This increase was primarily driven by an increase in HEPLISAV-B demand and market share gains in the U.S. in 2021, compared to 2020;
- In April 2021, we announced the results of the post-marketing study assessing the rates of occurrence of acute myocardial infarction ("AMI") in persons receiving HEPLISAV-B compared with Engerix-B. The results provided evidence there is no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B; and
- In October 2021, the U.S. Centers for Disease Control and Prevention’s (“CDC”) Advisory Committee on Immunization Practices (“ACIP”) recommended that all adults aged 19-59 be vaccinated against hepatitis-B. This universal recommendation created a significantly expanded market opportunity in the U.S., compared to the more limited prior recommendation to vaccinate at-risk populations, which we believe has greatly simplified prescribing practices.

Expand CpG 1018 Adjuvant Supply Business for COVID-19 Vaccines

- We recognized approximately $375.2 million in product revenue related to sales of CpG 1018 adjuvant to our global portfolio of partners developing COVID-19 vaccines during the year ended December 31, 2021. This represented a transformative increase compared to $3.3 million in adjuvant sales during the year ended December 31, 2020;
- Two of our adjuvant collaborators’ COVID-19 vaccine candidates, adjuvanted with CpG 1018, were approved for emergency use during the year ended December 31, 2021; additional collaborators’ successful phase 3 clinical data consistently demonstrated the value of CpG 1018 adjuvant across multiple vaccine platforms; and
- We continued to expand our manufacturing capacity to meet our partners’ needs for adjuvant in 2022 and beyond.

Drive Innovation Through Clinical Pipeline Expansion and Discovery

- We continued enrollment and made progress on our Tdap-1018 phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity of the vaccine, with topline data in adults and adolescents expected during 2022;
- In September 2021, we entered into a fully-funded collaboration with the U.S. Department of Defense to conduct a Phase 2 clinical trial for a plague vaccine adjuvanted with CpG 1018, which is expected to start in 2022;
- In January 2022, we announced the initiation of a phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity of our investigational shingles vaccine candidate adjuvanted with CpG 1018; and
- During the year, we further invested in our pre-clinical and clinical collaborations and discovery efforts, including our ongoing collaboration with Mount Sinai investigating universal and seasonal influenza.

Corporate and Financial Highlights

- We delivered net income of $76.7 million during the year ended December 31, 2021, representing our first full year of profitability;

- We generated $335.5 million in positive cash flow from operations during the year ended December 31, 2021, and ended the year with $546.0 million in cash, cash equivalents and marketable securities;
- We issued $225.5 million in 2.50% convertible senior notes due 2026. We used $190.2 million of the net proceeds to repay, in full, our previously outstanding 9.5% term loan due 2023, and $27.2 million to pay the costs of capped call transactions; and
- We increased the funding under our arrangement with Coalition for Epidemic Preparedness Innovations ("CEPI") in May 2021 to approximately $176.4 million, which supported the advance manufacturing cost of CpG 1018 adjuvant sold to or reserved for certain of our collaborators working to advance COVID-19 vaccine candidates, adjuvanted with CpG 1018.

Impact of COVID-19 Pandemic to our Business

Significant uncertainties remain with respect to the extent and duration of the impact of COVID-19 on our business and operations. The pandemic has resulted in changes to our business and operations which impacted our financial condition and results of operations for the year ended December 31, 2021, and 2020, and it may have a material adverse impact on our business and financial condition in the future. We continue to closely monitor the impact of the evolving effects of the COVID-19 pandemic on our business. In the process, we have made proactive efforts designed to help protect the health and safety of our workforce, as well as those of patients and healthcare professionals, while preserving the continuity of our business operations and advancing our goal of bringing important new vaccines to patients as rapidly as possible. While adult hepatitis B vaccine utilization rates have continued to stay below pre-pandemic levels, we are starting to see a recovery in such utilization from all-time lows. Additionally, HEPLISAV-B continues to gain market share in the U.S. hepatitis B adult vaccine market. The impact of COVID-19 on our business and financial condition is more fully described below in Part II, Item 7: *Management's Discussion and Analysis of Financial Condition and Results of Operations.*

OUR STRATEGY

Our vision is to become a leading vaccines company dedicated to developing and commercializing innovative vaccines in areas of significant unmet need, leveraging our demonstrated expertise and capabilities in vaccines and our proven vaccine adjuvant technology. Our strategy is focused on three core priorities: drive growth in our HEPLISAV-B vaccine, execute on our CpG 1018 adjuvant supply business and drive innovation through clinical pipeline expansion and discovery. Key elements of our strategy include:

- driving growth in our HEPLISAV-B vaccine (i) in the U.S. through expansion of overall market share and market share for the accounts which we target directly with our field-based salesforce and (ii) collaborating with global partners who share our vision, values, culture, and processes to develop and commercialize our HEPLISAV-B vaccine outside of the U.S.;
- delivering our proprietary CpG 1018 adjuvant to a diverse portfolio of global collaborators for COVID-19 vaccine development;
- expanding our clinical research pipeline by leveraging our demonstrated expertise and proven adjuvant technology in areas of unmet need, including for improved vaccines that may provide greater immunogenicity, lower reactogenicity and longer immune durability compared to currently marketed products;
- assembling a passionate team with demonstrated clinical and commercial success in discovering, developing and marketing vaccines that protect the world against infectious diseases;
- evaluating innovative, externally developed products for in-licensing or acquisition opportunities, with priority given to vaccine assets that address clear unmet need, provide scientific innovation, sound mechanistic rationale, a strong clinical safety profile, and a clear development path towards commercialization in disease areas primarily managed by our existing field-based salesforce footprint; and
- executing our strategy with our stockholders' long-term interests in mind and focusing on long-term, sustainable value creation over time.

HEPLISAV-B (Hepatitis B Vaccine, (Recombinant), Adjuvanted)

Our first commercial product, HEPLISAV-B (Hepatitis B Vaccine, (Recombinant), Adjuvanted), is approved by the United States Food and Drug Administration ("FDA") and the European Commission for prevention of infection caused by all known subtypes of HBV 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. HEPLISAV-B and each of the vaccines it directly competes against use rHBsAg to elicit an immune response to the virus.

About Hepatitis B

Hepatitis B is a potentially life-threatening liver infection caused by the HBV which may cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. There is no cure for hepatitis B, but the disease can be prevented through effective vaccination. The World Health Organization ("WHO") and the 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. The WHO estimates that worldwide, approximately 296 million people were living with chronic hepatitis B in 2019. In addition, the CDC estimated that in 2016 approximately 862,000 people in the U.S. were living with HBV infection. There were a total of 3,322 new cases of acute hepatitis B reported to the CDC in 2018. However, after adjusting for under-ascertainment and under reporting, the CDC estimated that 21,600 acute hepatitis B cases occurred in the U.S. in 2018.

Recommendations for Adult Vaccination to Prevent Hepatitis B

The CDC's ACIP unanimously voted at its November 2021 meeting to recommend that all adults 19 to 59 years of age should receive a hepatitis B vaccination. This universal recommendation greatly simplifies the identification of patients who need a hepatitis B vaccine compared to the previous risk-based recommendation, and significantly expands the number of adults in the United States who should be vaccinated against hepatitis B under CDC recommendation.

This recommendation is a significant milestone for hepatitis B prevention, making hepatitis B the fifth vaccine routinely recommended for adult immunization along with influenza, Tdap, shingles and pneumococcal. Based on this opportunity, we have begun to launch innovative marketing campaigns targeting consumers and healthcare providers to increase the awareness of HEPLISAV-B as the only two-dose hepatitis B vaccine option, with broad protection across most patient types.

Protection Against Hepatitis B by HEPLISAV-B

The approval of HEPLISAV-B by the FDA was based on data from three Phase 3 non-inferiority trials involving 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%).

Dynavax has worldwide commercial rights to HEPLISAV-B. In addition to HEPLISAV-B, there are four other vaccines approved for the prevention of hepatitis B in the U.S.: Engerix-B and Twinrix® from GlaxoSmithKline plc (GSK), Recombivax-HB® from Merck & Co. ("Merck") and PreHevbrio™ from VBI Vaccines Inc. HEPLISAV-B is currently approved in the U.S. and the EU for the prevention of hepatitis B in adults. We are also considering additional territories where it would be commercially feasible to market HEPLISAV-B.

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. Our field sales force of approximately 100 people are targeting customers that we believe represent, in the aggregate, approximately 60% of hepatitis B vaccine doses administered in the U.S., with an overall objective to increase market share.

We continue to explore ways to enhance the clinical profile of HEPLISAV-B. We completed an open-label, single arm study of a 4-dose regimen of HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis. Final immunogenicity results included a seroprotection rate of 89.3% with high levels of anti-HBs antibodies. Safety data showed HEPLISAV-B was well tolerated and no safety concerns were observed. 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 patients. 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 75%.

PROPRIETARY CPG 1018 VACCINE ADJUVANT

We believe the favorable immunogenicity and safety results achieved with HEPLISAV-B utilizing our CpG 1018 adjuvant support our efforts to develop it as a broadly useful vaccine adjuvant platform. CpG 1018 adjuvant has an established profile for the potential development of safe and effective vaccines. It 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. This results in potent adjuvant activity for antibody responses. In HEPLISAV-B, our CpG 1018 adjuvant drives faster and consistently higher rates of seroprotection than Engerix-B, even in the elderly and populations known to be less responsive to other vaccines. CpG 1018 adjuvant differentially elicits a preferred T Helper 1 ("Th1") cell polarized response and drives protective antibody production. CpG 1018 adjuvant has a large safety database that indicates 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 flu, other infectious diseases, and particularly COVID-19 across a variety of vaccine platforms. Data from studies in non-human primates demonstrate our CpG 1018 adjuvant can elicit a robust immune response to COVID-19 and protect animals from infection in challenge studies. Results from Phase 2 and 3 human clinical studies demonstrated CpG 1018 adjuvanted vaccines induced a high level of efficacy and strong immune responses, including neutralizing antibodies and Th1-biased cell-mediated immunity, and demonstrated a favorable safety and tolerability profile.

CpG 1018 Adjuvant Supply Partnerships for COVID-19 Vaccine Development

To support the fight against COVID-19, we have entered into certain supply relationships with a diverse portfolio of vaccine developers to supply CpG 1018 adjuvant for their use in development and/or commercialization of COVID-19 vaccines. To-date, two of our supply partners' vaccine candidates utilizing CpG 1018 adjuvant, have been approved for emergency use. Additionally, Phase 3 clinical data from other partnered programs consistently demonstrated the value of our adjuvant across multiple vaccine platforms with additional regulatory authorization for partners' COVID-19 vaccines anticipated in 2022. We continue to expand manufacturing capacity to meet our collaborators' needs for our adjuvant in 2022 and beyond.

Clover Biopharmaceuticals

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with Clover's COVID-19 vaccine candidate, SCB-2019 ("Clover Supply Agreement"). Under the Clover Supply Agreement, Clover has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI"), for use in Clover's commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant. The Clover Supply Agreement also provides specified terms for Clover to order and take delivery of additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In September 2021, Clover reported that SCB-2019 achieved the primary and secondary efficacy endpoints, with a favorable safety profile, in a global Phase 2/3 clinical trial.

Biological E. Limited

In July 2021, we entered into an agreement with Biological E. Limited ("Bio E"), for the commercial supply of CpG 1018 adjuvant, for use with Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™ (the "Bio E Supply Agreement"). Under the Bio E Supply Agreement, Bio E has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides specified terms for Bio E to order and take delivery of additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In December 2021, CORBEVAX received approval for emergency use from the Drugs Controller General of India.

Medigen Vaccine Biologics

In February 2021, we entered into a Supply Agreement with Medigen Vaccine Biologics (Medigen) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen's COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant, MVC-COV1901, for delivery in the first and second quarters of 2021. In August 2021, we entered into a second supply agreement to manufacture and supply additional specified

quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021. In August 2021, Medigen launched MVC-COV1901 after receiving Taiwan Emergency Use Authorization and approval for inclusion in Taiwan's COVID-19 vaccine immunization program.

Valneva Scotland Limited

In the third quarter of 2020, we entered into a commercial supply agreement with Valneva Scotland Limited (”Valneva”) to supply CpG 1018 adjuvant for its SARS-COV-2 vaccine candidate, VLA2001, in connection with Valneva’s supply agreement with the United Kingdom Government and subject to the terms of such agreement (“Valneva Supply Agreement”). In September 2021, the United Kingdom Government terminated its supply agreement with Valneva. In October 2021, Valneva reported that VLA2001 met both co-primary endpoints in the COV-COMPARE trial, and that VLA2001 was well-tolerated, demonstrating a statistically significant better tolerability profile compared to active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S).

In October 2021, we entered into a letter agreement (the “Valneva Amendment”), amending the Valneva Supply Agreement. Under the Valneva Amendment, we and Valneva agreed to the cancellation of the two then-outstanding purchase orders for CpG 1018 adjuvant under the Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment, and Valneva concurrently committed to purchase a reduced amount of CpG 1018 adjuvant under a new purchase order. We were entitled to retain the advance payments made by Valneva under such cancelled purchase orders to the extent such advance payments did not count towards the advance payments due under the Valneva Amendment.

Our Vaccine Research and Development Pipeline

We are building an innovative pipeline of investigational vaccine product candidates, leveraging our proven adjuvant technology. A summary of our pipeline programs follows:

Tdap Vaccine Phase 1 Study

Pertussis (whooping cough) is a serious illness in people of all ages and can be life-threatening, especially in infants. Whooping cough is caused by the highly contagious respiratory bacterium, *Bordetella pertussis*. People with pertussis usually spread the disease to others by coughing, sneezing or spending time in the same breathing environment. According to the CDC, there are an estimated 24.1 million cases of pertussis and about 160,700 deaths per year globally. The resurgence of B. pertussis in multiple countries has been attributed to the Tdap vaccine’s limited duration of protection and inability to block nasal colonizing infections, thereby failing to alter transmission. Our Tdap booster vaccine candidate adjuvanted with CpG 1018 is anticipated to improve the durability and protection against pertussis colonization in the upper airways by redirecting T cell responses and enhancing protective antibody responses in a booster vaccine. Initial proof-of-concept preclinical animal model data demonstrated that inclusion of CpG 1018 adjuvant in prime/boost vaccinations reduces bacterial burden in the upper and lower airways compared Tdap vaccination alone.

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 including Tdap booster adjuvated with CpG1018. Topline data is expected in 2022 from our ongoing Tdap-1018 phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity in adults and adolescents. Under the collaboration, we have exclusive worldwide rights to commercialize the vaccine, except that SIIPL has exclusive rights to distribute in India and to fulfill WHO/United Nations Children's Fund (“UNICEF”) tender contracts. Each party is responsible for clinical development cost in their respective territories.

Herpes Zoster Virus (Shingles) Vaccine Phase 1 Study

Shingles is an extremely painful consequence of the reactivation of a latent varicella-zoster virus (“VZV”) infection, with attacks leading to potential complications including chronic pain. The current shingles vaccine market is approximately $2 billion and expected to grow over time. Our CpG 1018 adjuvant has demonstrated its ability to enhance the immune response without excessive reactogenicity in both HEPLISAV-B and multiple COVID-19 clinical trials. Importantly, CpG 1018 has shown the ability to generate high levels of CD4+-cells which have been demonstrated to be key cell types in controlling latent VZV infection to avoid reactivation leading to shingles, with potentially lower reactogenicity compared to the current standard of care.

In January 2022, we announced the initiation of a phase 1 clinical trial of our shingles vaccine candidate, adjuvanted with CpG 1018. The global phase 1 study is designed to evaluate safety, tolerability and immunogenicity of the vaccine

candidate which is comprised of glycoprotein E (gE) plus CpG 1018 adjuvant. Topline data from this trial is expected by the end of 2022.

U.S. Department of Defense (Plague Vaccine) Phase 2 Study

In September 2021, we entered into an agreement with the U.S. Department of Defense ("DoD") for the development of a recombinant plague vaccine adjuvanted with CpG 1018 for approximately $22.0 million over two and a half years. Under the agreement, we will conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine to show that two doses of CpG 1018 adjuvanted vaccine is non-inferior compared to three doses of the aluminum-adjuvanted vaccine. We anticipate the Phase 2 trial will commence in 2022.

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, 2021, our intellectual property portfolio included over 25 issued U.S. patents, over 60 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 expiration of or decision to discontinue maintenance of older foreign patents that were not relevant to our active vaccine programs. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that expire in 2032.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued in the U.S. are effective for 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 2022 to 2042.

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, reissue or opposition 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 collaborators, 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. For example, while we recently announced a new shingles vaccine candidate, around the same time, Pfizer and Biontech also announced competing shingles programs. The approved products from these programs will all need to compete with a single approved vaccine currently available in the U.S.

We also believe our CpG 1018 adjuvant, which we use in our own products and product candidates and provide to our collaborators, is as or more effective than other available adjuvants and, being a yeast-derived product, is far more sustainable that other available products that are derived from, for example, shark squalene or tree bark. Regardless, there can be no guarantee that we can compete with other companies for sales of adjuvant, or any approved vaccine.

Competition for HEPLISAV-B

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 the U.S. 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 a majority of 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.

Competition for our adjuvant supply supporting COVID-19 and our development pipeline including pertussis, shingles and other potential pipeline indications

We are also in competition with companies developing vaccines, and vaccine adjuvants, generally, including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Novartis International AG, 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, 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, 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 (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 ("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 ("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, as well as their covered subcontractors. 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 ("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 ("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), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and information regarding ownership or investment interests held by such physicians and their immediate family members. The federal government discloses the reported information on a publicly available website. Certain states, such as Massachusetts, also make the reported information publicly available. In addition, there are state and local laws that require pharmaceutical representatives to be licensed and comply with codes of conduct, transparency reporting, and other obligations. These laws may adversely affect our sales, marketing, and other activities with respect to our products in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

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

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

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.

Coverage and Reimbursement. Sales of any marketed product, in particular for HEPLISAV-B, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any marketed product or a decision by a third-party payor not to cover a market product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

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 concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, U.S. Department of Health and Human Services ("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 until January 1, 2023. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform 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. For example, 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". On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 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 possible that the ACA will be subject to judicial or Congressional challenges in the future.

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, will remain in effect through 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. Further, Congress is considering additional health reform measures.

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 and conduct fill/finish operations. We also rely on a single supplier to produce our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators, and have established an additional qualified supplier to produce CpG 1018 adjuvant for our collaboration partners. 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. 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 and Ethics ("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 "Investors" and within that under the header "Corporate Governance Documents." 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. Access to our offices has been limited to essential workers since the beginning of the pandemic. We do not plan to have our headquarter-based employees return to our headquarters full-time once the pandemic subsides. This transition to a largely virtual environment further helps reduce congestion and pollution. Additionally, we have plans in 2022 to significantly reduce the size of our headquarters office space which will further reduce our carbon footprint. 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, 2021, we had 311 employees, comprised of 201 employees in the U.S., including 96 members of our field sales team located throughout the U.S., as well as 110 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., M.D. or J.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

Our regrettable turnover rate for 2021 was 12.0% in the U.S. and less than 7.7% 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 2.6 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 2021, an additional 28 leaders and key contributors completed a leadership development program.

In 2021 we offered a diversity and inclusion program called Awareness & Understanding in Action to our U.S.-based employees. This program consisted of five modules facilitated by an external Diversity, Equity and Inclusion ("DEI") consultant. Later in the year we implemented the following three global DEI Commitments:

- Fostering a culture where all employees are recognized and appreciated for the unique individuals they are and for their accomplishments in the workplace.
- Providing education to our employees on the negative effects of unconscious bias.
- Building and sustaining a team filled with a diversity of personal experiences, backgrounds, and perspectives.

In 2021 we also partnered with certain non-profit organizations committed to addressing the impact of poverty and inequality in our communities and we added two additional paid days for our employees to volunteer in their communities each year.

Response to the COVID-19 pandemic

In response to the COVID-19 pandemic, we moved to a virtual working model in the U.S. and through work-from-home and creative scheduling efforts, we continued to reduce the number of employees required to be onsite each day in our Düsseldorf manufacturing facility by approximately 50%. Also, in response to the pandemic we implemented a wellness mobile phone application for employees with free exercise, nutrition and other health related resources. We held several internal competitions among employees and rewarded employees for making healthy lifestyle choices. In the U.S. we implemented an additional mental health benefit providing greater access to resources and care for our employees and their family members.

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

An investment in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, in addition to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes, before making an investment decision. The risks described below are not the only ones facing us. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

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 these marketplaces. 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 in the U.S. or elsewhere will require significant resources and time and, while our personnel are experienced with respect to marketing of healthcare products, because HEPLISAV-B is our 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 the long term. Additionally, while we have received European approval for HEPLISAV-B and we entered a commercialization agreement for the marketing and distribution of HEPLISAV-B in Germany in May 2021, we have never launched a product in the European Union before and there can be no certainty that we will succeed in our European launch efforts. 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 fail to complete or maintain some or all of these important contracts on favorable terms or at all, or that in a potentially evolving reimbursement environment, our efforts may fail to overcome established competition at favorable pricing or at all.

We converted our contracted U.S. field sales team into full-time employees in the second quarter of 2019. Before then we had not previously employed an in-house field sales team, and thus have limited experience in overseeing and managing an employed salesforce. In 2021 we significantly expanded our field sales force. It will take time for this expanded team to generate significant sales momentum, if it does so at all. In addition, retention of capable sales personnel may be more difficult as we focus on 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 all adults aged 19-59, including patients with diabetes, receive hepatitis B vaccinations, we are unable to predict how many of those patients may actually 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 relatively new entrant in established distribution channels for vaccine products; and
- whether we will maintain sufficient financial resources 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 previously paused in-person customer interactions in healthcare settings and generally used electronic communication, such as emails, phone calls and video

conferences. We may be required to do again so in the future. Many healthcare 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. 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 initially restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in March 2020. As states began phasing out these restrictions, medical centers began operating under limited capacity and strict social distancing rules. The overall impact has generally resulted in significantly reduced utilization of all adult vaccines (other than COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of 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. There can be no assurance of the timing or likelihood for adult vaccine utilization rates to return to pre-pandemic levels.

Governments influence the price of medicinal products in the European Union through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Even though we have been granted a marketing authorization in the European Union for HEPLISAV-B, we have yet to obtain reimbursements and pricing approval in any European Union member state. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other European Union member states allow companies to fix their own prices for medicines, but monitor and control company profits. Any delay in being able to market our products in the European Union or elsewhere will adversely affect our business and financial condition.

If we, or our partners, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the U.S. and elsewhere, 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 COVID-19 virus and its variants, 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 and has continued to do so since. 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 allowing or significantly reduced access to their facilities for non-COVID-19 related business. Thus, our field sales and medical science employees have increased their use of telephone and web-based means 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 COVID-19 vaccines), including HEPLISAV-B, since the end of the first quarter of 2020. 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. Utilization rates for adult vaccines (other than COVID-19 vaccines) are well below pre-pandemic levels. Prolonged disruptions would likely materially and negatively impact our business, operating results and financial condition.

If the effect of any quarantines, shelter-in-place, executive and similar government orders related to COVID-19 increase, they could impact personnel at our manufacturing facility in Germany and third-party manufacturing facilities in the United States or abroad. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B or CpG 1018 adjuvant sufficient to meet demand.

The spread of COVID-19, which has caused a broad impact globally, has resulted in changes to our business and operations which has impacted our business and operations and may materially affect us economically in the future. While the potential economic impact, and the duration of such impact, brought by the COVID-19 pandemic 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 continue to emerge. 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, sales of CpG 1018 adjuvant and our total 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 and severity of the outbreak including current and future variants, 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 U.S. 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 our HEPLISAV-B vaccine and our CpG 1018 adjuvant, 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 will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to successfully commercialize our HEPLISAV-B vaccine and CpG 1018 adjuvant, 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, retain and integrate additional management, administrative and sales and marketing personnel, or secure sufficient or timely supply from third party service and product providers, and our failure to accomplish any of these activities could prevent us from successfully growing or our company or maintaining the same level of commercial growth.

As we plan for broader commercialization of our HEPLISAV-B vaccine and for expanded capacity to manufacture our CpG 1018 adjuvant, 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 CpG 1018 adjuvant, to support market share gains or potential vaccine collaborations in 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 adjuvant 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 or customers 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 the adjuvant or any other product does not materialize in the volumes we are expecting or at all.

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 adjuvant, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain quantities and meet 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 obligations, 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.

Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.

A substantial portion of our revenue for the foreseeable future may depend on sales of CpG 1018 adjuvant, which are difficult to predict. For example, as of December 31, 2021, we received advanced payments from certain of our customers to purchase specified quantities of CpG 1018 adjuvant which were recorded as deferred revenue until we deliver the adjuvant and meet all criteria to recognize revenue. In accordance with our stated revenue policy, we expect to record revenue for these contracts upon meeting all of the criteria for revenue recognition under Accounting Standards Codification 606, which includes, among other criteria, the transfer of control for CpG 1018 adjuvant to our customer. The occurrence and timing of such transfer of control can be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. We expect that our visibility into future revenue relating to sales of CpG 1018 adjuvant, including volumes, prices and timing, will continue to be limited and could result in significant, unexpected fluctuations in our quarterly and annual operating results.

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, during the year ended December 31, 2021, sales of CpG 1018 accounted for 85% of our overall revenue, and one CpG 1018 customer accounted for 42% of our revenue. If orders from our top customers or the number of CpG 1018 collaborations are reduced or discontinued, our revenue in future periods may materially decrease. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Similarly, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on any particular past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our products 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 products or product candidates in commercial quantities. With respect to HEPLISAV-B, we use a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture or have manufactured 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 good manufacturing practice ("GMP") in order to meet market demand.

Historically, we have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce (i) our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators and (ii) our pre-filled

syringe presentation. Recently, we qualified a second supplier to manufacture CpG 1018 adjuvant, but have a limited operating relationship with them. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing suppliers for CpG 1018 adjuvant, we would have to establish an alternate qualified manufacturing capability ourselves, which would result in significant additional operating costs and delays in manufacturing HEPLISAV-B, or CpG 1018 adjuvant, and developing and commercializing our and our collaborators' 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 our products or our and our collaborators' product candidates and could result in significant expense.

We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop vaccines 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 adjuvant or otherwise are inadequate, we may be unable to realize recurring commercial benefit from the development of any vaccines containing CpG 1018 adjuvant.

As part of our business, we are working to develop our CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, plague, Tdap, seasonal influenza, universal influenza and shingles. There are risks and uncertainties inherent in vaccine research and development, including the timing of completing vaccine development, the results of clinical trials, whether a vaccine will be approved for use, the extent of competition, government actions and whether a vaccine can be successfully manufactured and 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 our adjuvant. 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. Our collaborators may not purchase as much adjuvant as we anticipate, and they may delay placing orders or delay taking certain deliveries under certain circumstances which can affect our revenue recognition. If a collaborator fails to conduct collaborative activities successfully, the development and commercialization of a vaccine could be delayed, and may not occur at all. For example, as of December 31, 2021, only two of our collaborators have received emergency use authorization from an applicable regulatory authority for any vaccine for COVID-19 containing our adjuvant. We have historically relied on a single supplier to produce our CpG 1018 adjuvant, and only recently have qualified an alternate supplier to produce the adjuvant with whom we have a limited operating relationship. If we were unable to maintain our existing suppliers for the adjuvant, we would have to establish and maintain 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 sufficient adjuvant at a cost, quantity and quality similar to that available from our current third-party suppliers, or at all, and even if we are successful in adding an additional supplier, there is no guarantee such supplier will be able to manufacture compliant supplemental quantities sufficient to support commercial demand, to the extent it materializes, and in the timeframes required.

Our adjuvant has no composition of matter patent protection. We have filed patent applications claiming compositions and methods of use of CpG 1018 adjuvant for COVID-19 and other vaccines. Such patents may or may not be allowed. 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 adjuvant. If we are unable to adequately obtain or enforce our proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant, and we may not have the ability to prevent others from developing or commercializing a vaccine containing the adjuvant. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

Furthermore, restrictive government actions related to potential waivers of intellectual property rights in the case of national emergencies or in other circumstances, such as imposition of compulsory licenses related to COVID-19 vaccines, as well as other regulatory initiatives, may result in a general weakening of our or our collaborators' intellectual property protection or otherwise diminish or eliminate our or our collaborators' ability to realize any commercial benefit from the

development of a COVID-19 vaccine containing CpG 1018. This may, in turn, adversely impact the demand for CpG 1018, which would have a material adverse effect on our business, results of operations, and financial condition.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third-party payors, which may make it difficult or impossible to sell certain of our products 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. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. 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 adjuvant that may be required in the event that our CpG 1018 adjuvant 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. We may seek such grants in the future. 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 our control over the manufacturing and distribution of grant-funded products. Failure to agree with such requirements, may result in us not receiving some or all of the grant.

We are subject to ongoing FDA and EMA 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 regulatory issues 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 were required to conduct an observational comparative study of HEPLISAV-B to Engerix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018, concluded in November 2020 and the final study report has been submitted to the FDA. We are also committed to conducting 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 and/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.

Similar post-marketing obligations and commitments exist in the European Union. For example, we are required to submit periodic safety update reports to the EMA and to keep an up to date risk management plan that takes into account new information that may lead to a significant change in the risk/benefit profile of HEPISLAV-B. Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can result in significant financial penalties.

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 in the United States and the European Union. 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 limit 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 commercialized outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies who market abroad. 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 U.S.

We are also in competition with companies developing vaccines and vaccine adjuvants, generally including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Novartis International AG, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson and VBI. We will likely compete with several of these companies in the hepatitis space, Tdap space, shingles space and spaces occupied by any other product candidates we ultimately choose to advance through our pipeline in the future.

Products in our clinical pipeline, if approved, will also face competition from competitors who have competing clinical programs or already approved products. Existing and potential competitors or other market participants 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 as needed, enter into collaborative arrangements, sell our product candidates or generate revenues.

Despite recent profitability, we have incurred annual net losses in each year since our inception and anticipate that we could continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and/or continue to sell significant quantities of our CpG 1018 adjuvant, and if we are unable to sustain profitability, the market value of our common stock will likely decline.

We have generated limited revenue from the sale of products and, prior to January 1, 2021, have incurred losses in each year since we commenced operations in 1996. Our net income for the year ended December 31, 2021 was $76.7 million compared to net loss of $75.2 million for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of $1.2 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S., we have in the past, and could in the future, incur operating losses. 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 adjuvant have generated significant 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. and abroad may further affect costs or losses related to commercialization. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine products or other products we may choose to offer in the future, we are unable to predict the extent of any future losses or when, if ever, we will become profitable on an annual basis, or, that if we are able to reach consistent 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 on a consistent basis, we may require substantial additional capital to finance our operations.

As of December 31, 2021, we had $546.0 million in cash, cash equivalents and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. For the year ended December 31, 2021, we had net income of $76.7 million. As of December 31, 2021, we had an accumulated deficit of $1.2 billion. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable and past results are not a reliable indicator of future performance. Further, we expect to continue to incur substantial expenses as we continue to invest in the commercialization and development of HEPLISAV-B and our CpG 1018 adjuvant, clinical trials for our pipeline candidates, and other development. 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 or otherwise. 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 any requests that 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 develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates outside of the U.S. and Europe, 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 products or product candidates.

We may seek to introduce HEPLISAV-B, or any other product candidates we may develop, to various additional markets outside of the U.S. and Europe. Developing, seeking regulatory approval for and marketing our product candidates outside of 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;
- foreign tax compliance and 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 the European Union, 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, even if we undertake these efforts.

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 have uncertain outcomes.

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA (and other regulatory agency) 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 regulatory 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 otherwise unavailable for 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.

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. Even if we complete all such activities without issue, final results may not actually support approval of a particular product candidate.

HEPLISAV-B and most of our earlier stage programs rely on oligonucleotide TLR agonists. In the event of serious adverse event data relating to TLR agonists we may be required 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.

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 products and 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 or product candidates, 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 products or 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 or manage 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 have and may in the future 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 product candidates, obtain regulatory approvals and successfully manufacture and commercialize the products developed from product 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.

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 Penalties 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), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created, among other things, new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements 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 General Data Protection Regulation ("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 standard contractual clauses, or 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.

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 have been executive, legal and political challenges to certain aspects of ACA. For example, 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 ("Tax Act") included 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 ("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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and 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, will remain in effect through 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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 concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services ("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 until January 1, 2023. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other reform 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.

In connection with our work with the U.S. Department of Defense, we have become a defense contractor, and are therefore subject to new administrative burdens and control requirements in connection with the maintenance of that relationship.

In September of 2021, we entered into an agreement with the U.S. Department of Defense ("DoD") relating to the conduct of a clinical trial in connection with the development of an improved plague vaccine. In connection with this agreement we became subject to new administrative and control requirements, including certain reporting obligations as well as a requirement to develop, implement and maintain an ITAR compliance program, among other things. Further, if our efforts result in an improved plague vaccine and we enter into a supply agreement for finished plague vaccines with the DoD, we expect that such a supply contract would impose additional administrative, control, compliance and other obligations. We have limited experience developing and administering such programs. Development and maintenance of such programs can be burdensome and costly and there can be no guarantee that we will be able to maintain compliance with all of the terms of such an agreement. Failure to comply with these requirements could have a significant reputational or financial impact on our business and on our stock price.

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

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 or other dispute 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 have been, and in the future may become, 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 our CpG 1018 adjuvant.

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, our HEPLISAV-B and CpG 1018 adjuvant have 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 HEPLISAV-B and 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 HEPLISAV-B and CpG 1018. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that expire in 2032. 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. In addition, we may be subject to co-ownership of the underlying intellectual property with our collaborators and not the sole owner. 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 recurring 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 at all. For example, while many countries such as the U.S. 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, or may prohibit certain activities, 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;
- other parties may design around technologies we have licensed, patented or developed; and
- pending patent applications or issued patents may be challenged by third parties in proceedings, such as inter partes review, pre- and post-grant oppositions, and post grant review.

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 or other proprietary know-how 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.

We have in the past, and may in the future, rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to obtain or maintain them could severely harm our business.

Our current or future research and development efforts may depend in part upon our license arrangements for certain intellectual property owned by third parties. Our dependence on these licenses could subject 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 could 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 such agreements could allow 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 or at all. In addition, 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 develop or commercialize certain of 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.

Risks Related to 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 the COVID-19 pandemic on our HEPLISAV-B vaccine, CpG 1018 adjuvant, or other 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;
- the volume of trading in our common stock;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance; and
- industry conditions and general financial, economic and political instability, as well as developments with respect to the COVID-19 global pandemic, including but not limited to regulatory initiatives, such as the imposition of compulsory licenses related to COVID-19 vaccines, that may result in a general weakening of intellectual property protections.

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, interest rate increases and/or other tapering policies from the government, and other adverse effects or developments relating to the ongoing COVID-19 pandemic or general economic environment 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 & Company, LLC, under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million. As of December 31, 2021, we had $120.5 million remaining under our sales agreement with Cowen & Company, LLC. 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.

Risks Related to Our Outstanding Convertible Notes

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the $225.5 million in 2.50% convertible senior notes due 2026 (“Convertible Notes”), depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the notes for cash upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes.

Holders of the Convertible Notes will have the right, subject to certain conditions and limited exceptions, to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. Moreover, we will be required to repay the Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture governing the Convertible Notes or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture governing the Convertible Notes would constitute a default under the indenture governing the Convertible Notes. A default under the indenture governing the Convertible Notes or the occurrence of a fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes could constitute an event of default under any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Convertible Notes may adversely affect our financial condition and operating results.

As of October 1, 2021, the conditions allowing holders to convert all or any portion of their Convertible Notes were met, and holders of Convertible Notes are entitled to convert their Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Conversion of the Convertible Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.

The conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. As of October 1, 2021, the conditions allowing holders to convert all or any portion of their Convertible Notes were met. Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock.

Certain provisions in the indenture governing the Convertible Notes may delay or prevent an otherwise beneficial takeover attempt of us.

Certain provisions in the indenture governing the Convertible Notes may make it more difficult or expensive for a third party to acquire us. For example, the indenture governing the Convertible Notes will require us, subject to certain exceptions, to repurchase the Convertible Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Convertible Notes in connection with a make-whole fundamental change. A takeover of us may trigger the requirement that we repurchase the Convertible Notes and/or increase the conversion rate, which could make it more costly for a potential acquirer to engage in such takeover. Such additional costs may have the effect of delaying or preventing a takeover of us that would otherwise be beneficial to investors.

The Capped Calls may affect the value of the Convertible Notes and our common stock.

In connection with the issuance of the Convertible Notes, we have entered into capped call transactions with the option counterparties totaling $27.2 million (the "Capped Calls"). The Capped Calls cover, subject to customary adjustments, the number of shares of common stock that initially underlie the Capped Calls. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

In connection with establishing their initial hedges of the Capped Calls, we have been advised that the option counterparties and/or their respective affiliates entered into various derivative transactions with respect to our common stock concurrently with or shortly after the pricing of the Convertible Notes and/or purchased shares of our common stock concurrently with or shortly after the pricing of the Convertible Notes. In addition, the option counterparties and/or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions following the pricing of the Convertible Notes and prior to the maturity of the Convertible Notes (and are likely to do so on each exercise date of the Capped Calls, which are expected to occur during the 30 trading day period beginning on the 31st scheduled trading day prior to the maturity date of the Convertible Notes, or following any termination of any portion of the Capped Calls in connection with any repurchase, redemption or early conversion of the Convertible Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Convertible Notes.

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 (such as the ongoing COVID-19 pandemic) 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, have and could again in the future cause restrictions on supply chains, restrict 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. For example, the COVID-19 pandemic has generally resulted in significantly reduced utilization of all adult vaccines (other than the COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B.

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. In 2020, we 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, 2021, 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 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. In September 2021, we entered into a new Düsseldorf lease for the same space we previously leased, with the same landlord. The new lease will continue until December 31, 2031.

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 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 21, 2022, there were approximately 40 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

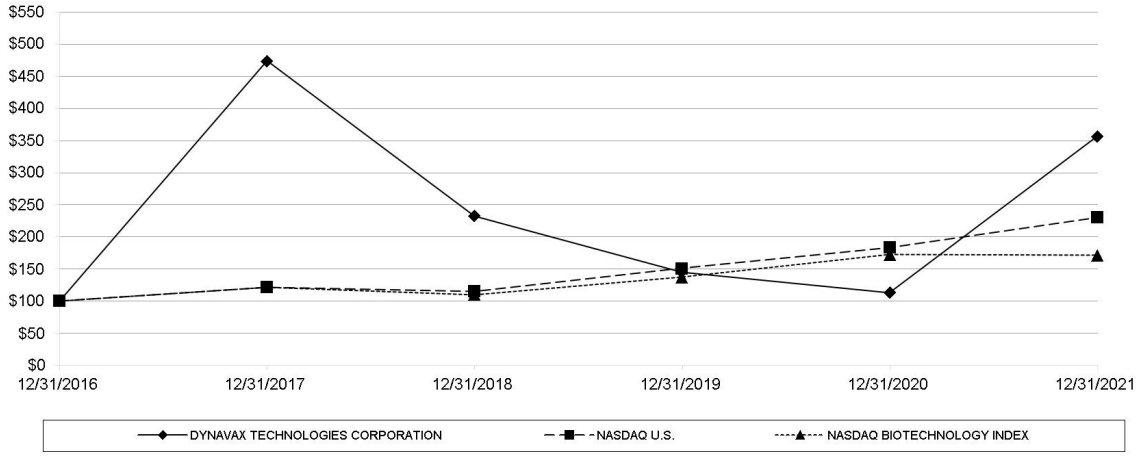
We have never paid any cash dividends on our common stock. We currently expect to retain future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Stock Performance Graph

The chart below compares total stockholder return on an investment of $100 in cash on December 31, 2016, for: our common stock, the Nasdaq Stock Market (U.S. companies), and the Nasdaq Biotechnology Index. All values assume reinvestment of the full amount of all dividends.

Note: Dynavax management cautions that the stock price performance shown in the graph below should not be considered indicative of potential future stock price performance.

COMPARISON OF 5 -YEAR CUMULATIVE TOTAL RETURN
AMONG DYNAVAX TECHNOLOGIES, NASDAQ MARKET INDEX, AND SIC CODE INDEX



ASSUMES $100 INVESTED ON DECEMBER 31, 2016
ASSUMES DIVIDENDS REINVESTED
FISCAL YEAR ENDING DECEMBER 31, 2021

This Section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of Dynavax Technologies Corporation under the Securities Act, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

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 innovative vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and European Union 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, plague, Tdap, seasonal influenza, universal influenza and shingles.

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. and the European Union.

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. We received Marketing Authorization approval of HEPLISAV-B in February 2021 from the European Commission for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. In May 2021, we entered into a commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany.

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, 2021, HEPLISAV-B product revenue, net was $61.9 million.

In January 2021, we entered into an agreement (the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant. In May 2021, we entered into the first amendment (the "Amendment") to the CEPI Agreement. The agreement enables CEPI to direct the supply of CpG 1018 adjuvant to CEPI partner(s). In exchange for reserving CpG 1018 adjuvant, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan of up to $176.4 million.

In July 2021, we entered into an agreement (the "Bio E Supply Agreement") with Biological E. Limited ("Bio E"), for the commercial supply of CpG 1018 adjuvant, for use with Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™. Under the Bio E Supply Agreement, Bio E has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides terms for Bio E to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In December 2021, CORBEVAX received approval for emergency use from the Drugs Controller General of India.

In June 2021, we entered into an agreement (the "Clover Supply Agreement") with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with its protein-based COVID-19 vaccine candidate, adjuvanted with our CpG 1018 adjuvant, SCB-2019. In September 2021, Clover reported that SCB-2019 achieved the primary and secondary efficacy endpoints, and with favorable safety profile, in a global Phase 2/3 clinical trial.

In February 2021, we entered into a Supply Agreement (“Medigen Supply Agreement”) with Medigen Vaccine Biologics (“Medigen”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen’s COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant, MVC-COV1901, for delivery in the first and second quarters of 2021. In August 2021, we entered into a second supply agreement (“Medigen Supply Agreement No. 2”) to manufacture and supply additional specified quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021. In August 2021, Medigen launched MVC-COV1901 after Medigen received Taiwan Emergency Use Authorization and approval for inclusion in Taiwan's COVID-19 vaccine immunization program.

In the third quarter of 2020, we announced a commercial supply agreement (the “Valneva Supply Agreement”) with Valneva Scotland Limited (“Valneva”) to cover the supply of CpG 1018 adjuvant for its SARS-COV-2 vaccine candidate, VLA2001, in support of its supply agreement with the United Kingdom Government and subject to the terms of such agreement. In September 2021, Valneva received a termination notice from the United Kingdom Government in relation to such supply agreement. However, Valneva continues the clinical development of VLA2001 and the pivotal Phase 3 trial for VLA2001, COV-COMPARE, remains ongoing at Public Health England. In October 2021, Valneva reported that VLA2001 met both co-primary endpoints in the COV-COMPARE trial, and that VLA2001 was well-tolerated, demonstrating a statistically significant better tolerability profile compared to active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S).

In October 2021, we entered into a letter agreement (the “Valneva Amendment”), amending the Valneva Supply Agreement. Under the Valneva Amendment, we and Valneva agreed to the cancellation of the two then outstanding purchase orders for CpG 1018 adjuvant under the Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment, while concurrently committing to purchase a reduced amount of CpG 1018 adjuvant under a new purchase order. We are entitled to retain the advance payments made by Valneva under such cancelled purchase orders to the extent such advance payments do not count towards the advance payment dues under the Valneva Amendment.

For the year ended December 31, 2021, CpG 1018 product revenue, net, was $375.2 million.

In September 2021, we entered into an agreement with the U.S. Department of Defense ("DoD") for the development of an improved recombinant plague vaccine adjuvanted with CpG 1018, whereby the DoD will provide funding of up to approximately $22.0 million over two and a half years. Under the agreement, we agreed to conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. We anticipate the Phase 2 trial will commence in 2022.

In May 2021, we issued $200.0 million aggregate principal amount of 2.50% convertible senior notes due 2026 (the “Convertible Notes”) in a private placement. The purchasers partially exercised their option to purchase additional Convertible Notes and we issued an additional $25.5 million of the Convertible Notes in May 2021. Total proceeds from the issuance of the Convertible Notes, net of debt issuance and offering costs of $5.7 million, were $219.8 million. We used $190.2 million of the net proceeds to repay, in full, our outstanding debt and other obligations under the Loan Agreement and $27.2 million of the net proceeds to pay the costs of the capped call transactions described below.

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers and other financial institutions, totaling $27.2 million (the “Capped Calls”). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

In May 2021, we repaid the term loans and paid-in-kind interest (collectively “Term Loans Principal”) under the Loan Agreement with CRG Servicing LLC (“Loan Agreement”), in full, using the net proceeds from the Convertible Notes issuance described above. In connection with the early repayment of the Term Loans Principal, during the three months ended June 30, 2021, we recorded $5.2 million loss on debt extinguishment related to the amount we paid to terminate the Term Loans Principal in excess of its carrying value at the time of the repayment. Our final payment of $190.2 million to CRG Servicing LLC satisfied all of our obligations under the Loan Agreement. With the full repayment of the Term Loans Principal, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

COVID-19 Update

The ongoing COVID-19 global pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 virus or current or newly discovered variants, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. We continue to assess the potential evolving impact of the COVID-19 pandemic on our business and operations.

To date, we and our distribution partners have been able to continue to supply HEPLISAV-B throughout the United States, and currently do not anticipate any interruptions in supply. Due to the ongoing COVID-19 global pandemic, most medical centers began restricting access to their facilities and focused on providing care to only the most severely affected patients, beginning in March 2020. As states began phasing out restrictions in the middle of 2020, medical centers have been operating under limited capacity or with strict social distancing rules. There has been a significant reduction in the utilization of adult vaccines (other than COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B which has impacted sales of HEPLISAV-B. While adult hepatitis B vaccine utilization rates have continued to stay below pre-pandemic levels, we are starting to see a recovery in such utilization from all-time lows. Additionally, HEPLISAV-B continues to gain market share in the U.S. hepatitis B adult vaccine market.

We are continuing to closely monitor the impact of the COVID-19 pandemic on our business and are taking proactive efforts to help 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 help protect the health and safety of our workforce, including a mandatory work-from-home policy for employees who can perform their jobs offsite and continue to actively evaluate a return to the office at an appropriate time. In the conduct of our business activities, we are also taking actions to help protect the safety of patients and healthcare professionals. In the early stages of the pandemic, our field-based personnel reduced in-person customer interactions in healthcare settings and primarily used 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 began conducting a greater proportion of their work from their homes and are facing additional demands on their time during the COVID-19 pandemic. While 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, impacted the effectiveness of our sales personnel, we have gradually moved back to in-person interactions in many cases. With the rise of new variants, and related precautions, however, our customers' procurement activities and those of our collaborators continue to be impacted which could negatively affect our overall product sales. It is possible that we may have to limit in-person engagement again in the future.

Our HEPLISAV-B post-marketing follow-up has been completed. In April 2021, we announced the results of the post-marketing study assessing the rates of occurrence of acute myocardial infarction ("AMI") in persons receiving HEPLISAV-B compared with Engerix-B. The results provided evidence there is no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B. We expect data from the autoimmune portion of our observational study to be available in the first quarter of 2022. Our HEPLISAV-B dialysis study has also been completed. Final immunogenicity results included a seroprotection rate of 89.3% with high levels of anti-HBs antibodies. Safety data showed HEPLISAV-B was well tolerated and no safety concerns were observed.

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.

We have been actively pursuing opportunities to collaborate with other organizations on the development of a COVID-19 vaccine, by leveraging CpG 1018 adjuvant, our toll-like receptor 9 ("TLR9") agonist, which is also used in our HEPLISAV-B product. Since the first half of 2021, we announced multiple collaborations focused on COVID-19 and we continue to work to identify other programs where CpG 1018 adjuvant can be utilized to enhance the immune response to a coronavirus vaccine or other vaccines. To date, two of our collaborators have received emergency use authorizations for their

COVID-19 vaccines, and we anticipate that more will be announced during 2022. We and our contract manufacturers are developing plans to help scale-up activities to support pandemic-level of production of our CpG 1018 adjuvant, as necessary to support these and any future collaborations. There can be no assurance we will be successful in our efforts to help develop or supply adjuvanted COVID-19 vaccines or other vaccines.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles. In doing so, we are required to make estimates and assumptions. Our critical accounting estimates are those estimates that involve a significant level of uncertainty at the time the estimate was made, and changes in them have had or are reasonably likely to have a material effect on our financial condition or results of operations. Actual results could differ materially from our estimates. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis.

See Note 2 to the Consolidated Financial Statements in this Annual Report on Form 10-K for a summary of our significant accounting policies.

Revenue Recognition

Product Revenue, Net – HEPLISAV-B

We recognize revenue when we transfer control of promised goods to the customer at the net sales price, which includes estimates such as product returns, chargebacks, discounts, rebates and other fees. While each item is more fully described in Note 2 to the Consolidated Financial Statements, the following items reflect the more critical and significant estimates used in the preparation of our consolidated financial statements. Our estimates of such items 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 accounts receivable reserves or revenue reserves accrual that we report in a particular period.

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

Chargebacks: Our customers subsequently resell our product to healthcare providers, pharmacies and others. In addition to distribution agreements with our 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. 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.

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.

Inventories, net

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

Stock-Based Compensation

The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes model requires us to make estimates and assumptions. Our estimate of volatility is based on the historical volatility of our stock price over the term of the awards. We derive the expected term assumption based on our historical settlement experience. 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. 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.

Income Taxes

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, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations.

Based on all available evidence, both positive and negative, and the weight of that evidence to the extent such evidence can be objectively verified, we believe that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more likely than not to be realized and, accordingly, we have determined a need for a full valuation allowance. Given our current earnings, we believe that, within the next twelve months, sufficient positive evidence may become available to allow us to reach a conclusion that a portion of the valuation allowance recorded against the deferred tax assets held may be reversed. A reversal would result in an income tax benefit for the quarterly and annual fiscal period in which we determine to release the valuation allowance. However, the exact timing and amount of a valuation allowance release are subject to change on the basis of the level of profitability that we actually achieve.

Recent Accounting Pronouncements

See Note 2 – Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements (Part II, Item 8 of this Form 10-K) for information regarding recent accounting pronouncements that are of significance, or potential significance to us..

Results of Operations

This section of this Form 10-K generally discusses 2021 and 2020 items and year-to-year comparisons between 2021 and 2020. Discussions of 2019 items and year-to-year comparisons between 2020 and 2019 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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 CpG 1018 adjuvant to our collaboration partners for use in their development and/or potential commercialization of COVID-19 vaccines. 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 2020 to 2021	
Revenues:	**2021**	**2020**	**2019**	**$**	**%**
HEPLISAV-B	$ 61,870	$ 36,030	$ 34,644	$ 25,840	72 %
CpG 1018	375,229	3,277	-	371,952	11,350 %
Total product revenue, net	437,099	39,307	34,644	397,792	1,012 %
Other revenue	2,343	7,244	575	(4,901)	(68)%
Total revenues	$ 439,442	$ 46,551	$ 35,219	$ 392,891	844 %

2021 versus 2020

HEPLISAV-B product revenue for the year ended December 31, 2021 increased compared to the same period in 2020. Approximately $21.4 million of the increase was due to higher volume driven by an increase in HEPLISAV-B demand and market share gains in the U.S. Approximately $4.5 million of the increase was due to higher net sales price.

In September 2020, we began selling our CpG 1018 adjuvant to our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. In 2021, we executed supply agreements with several major collaboration partners. The increase in CpG 1018 adjuvant product revenue for the year ended December 31, 2021, compared to the same period in 2020, was due to an increase sales volume as we continued to manufacture and ship CpG 1018 adjuvant pursuant to our supply and collaboration agreements.

The decrease in other revenue for the year ended December 31, 2021, compared to the same period of 2020, was due to the termination of an agreement with CEPI resulting in the recognition of $6.3 million in previously received reservation payments. We entered into a new agreement with CEPI in January 2021 (see Note 9 to the Consolidated Financial Statements). The decrease was partially offset by an increase in other revenue due to the recognition of $1.2 million, in the third quarter of 2021, in connection with the termination of a certain grant agreement. Other revenue also includes grant revenue from our agreement with the U.S. Department of Defense and collaboration revenue related to services performed under a collaboration agreement with Serum Institute of India Pvt. Ltd.

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 adjuvant 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 United States Food and Drug Administration (“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 2020 to 2021	
Cost of Sales - Product	**2021**	**2020**	**2019**	**$**	**%**
HEPLISAV-B	$ 26,999	$ 10,057	$ 10,172	$ 16,942	168 %
CpG 1018	146,573	1,353	-	$ 145,220	10,733 %
Total cost of sales - product	$ 173,572	$ 11,410	$ 10,172	$ 162,162	1,421 %

2021 versus 2020

For the year ended December 31, 2021, HEPLISAV-B cost of sales-product increased compared to the same period in 2020. Approximately $5.0 million of the increase was due to higher sales volume and approximately $3.7 million of the increase was due to higher unit costs. In addition, included in HEPLISAV-B cost of sales - product for the year ended December 31, 2021 was a $4.8 million of excess capacity charge in connection with an expansion project at our manufacturing facility in Düsseldorf. Additionally, due to the COVID-19 pandemic and its prolonged impact on vaccine utilization and corresponding revisions to our sales forecast, we recorded an approximately $2.6 million write-off to cost of sales – product associated with HEPLISAV-B slow moving short-dated inventory that had been manufactured prior to the beginning of the COVID-19 pandemic. We expect to incur additional excess capacity charge in 2022 as the manufacturing facility expansion project in Düsseldorf continues.

In September 2020, we began selling our CpG 1018 adjuvant to our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. In 2021, we executed supply agreements with several major collaboration partners. The increase in CpG 1018 adjuvant cost of sales-product for the year ended December 31, 2021, compared to the same period in 2020, was due to an increase sales volume as we continued to manufacture and ship CpG 1018 adjuvant pursuant to our supply and collaboration agreements.

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 2020 to 2021	
Research and Development:	**2021**	**2020**	**2019**	**$**	**%**
Compensation and related personnel costs	$ 12,136	$ 10,328	$ 21,933	$ 1,808	18 %
Outside services	15,767	16,064	25,437	$ (297)	(2)%
Facility costs	507	1,215	6,903	$ (708)	(58)%
Non-cash stock-based compensation	3,818	1,000	8,058	$ 2,818	282 %
Total research and development	$ 32,228	$ 28,607	$ 62,331	$ 3,621	13 %

2021 versus 2020

Compensation and related personnel costs and non-cash stock-based compensation for the year ended December 31, 2021 increased, compared to the same period in 2020, primarily due to higher headcount to support vaccine clinical and development activities. In addition, non-cash stock-based compensation for year ended December 31, 2020 included reversal of expenses related to cancellation of certain equity grants.

For the year ended December 31, 2021, outside services decreased, compared to the same period in 2020, due to (i) approximately $2.3 million decrease due to winding down of our immuno-oncology study (ii) offset by approximately $1.8 million increase in vaccine clinical and development activities.

Facility costs, which primarily comprise of occupancy and related expenses, decreased, as compared to the same period in 2020, due to lower overhead allocation to research and development functions.

We expect research and development expenses to increase in 2022 as we continue to advance our product candidates with CpG 1018 adjuvant through pre-clinical and clinical collaborations and additional discovery efforts.

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 2020 to 2021	
Selling, General and Administrative:	**2021**	**2020**	**2019**	**$**	**%**
Compensation and related personnel costs	$ 43,135	$ 31,191	$ 28,525	$ 11,944	38 %
Outside services	27,981	24,759	26,269	3,222	13 %
Legal costs	1,906	2,296	2,293	(390)	(17)%
Facility costs	12,240	11,425	7,675	815	7 %
Non-cash stock-based compensation	14,894	9,585	10,224	5,309	55 %
Total selling, general and administrative	$ 100,156	$ 79,256	$ 74,986	$ 20,900	26 %

2021 versus 2020

For the year ended December 31, 2021, compensation and related personnel costs increased, as compared to the same period in 2020, due to higher headcount in connection with the expansion of our field sales force in July 2021, increase in business travel as COVID-19 travel restrictions were easing and increase in recruiting expenses.

For the year ended December 31, 2021, outside services increased, as compared to the same period in 2020 primarily due to an overall increase in sales and marketing efforts, offset by $2 million decrease in the amount we paid to Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC in connection with the sale of our immuno-oncology compound, SD-101 in July 2020.

Facility costs, which primarily comprise of occupancy and related expenses, increased, as compared to the same period in 2020, due to higher overhead allocation to selling, general and administrative functions.

The increase in non-cash stock-based compensation for the year ended December 31, 2021, compared to the same period in 2020, was primarily due to higher headcount in connection with the expansion of our field sales force in July 2021. In addition, non-cash stock-based compensation for the year ended December 31, 2020 included reversal of expenses related to cancellation of certain equity grants.

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 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.

In September 2021, we received payment of $1 million from TriSalus for their meeting a pre-commercialization milestone which was recognized as a gain on sale of SD-101 assets our consolidated statements of operations.

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 terminated long-term debt agreement and Convertible Notes. Sublease income is recognized in connection with our sublease of office and laboratory space. Loss on debt extinguishment reflects the amount we paid to terminate our long-term debt in excess of its carrying value at the time of the extinguishment. 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 2020 to 2021	
	2021	2020	2019	$	%
Interest income	$ 140	$ 1,260	$ 3,370	$ (1,120)	(89)%
Interest expense	$ (11,176)	$ (19,062)	$ (16,977)	$ (7,886)	(41)%
Sublease income	$ 7,735	$ 7,706	$ 2,619	$ 29	0%
Loss on debt extinguishment	$ (5,232)	$ -	$ -	$ 5,232	NM
Change in fair value of warrant liability	$ (49,354)	$ 4,124	$ (7,500)	$ (53,478)	(1,297)%
Other	$ 922	$ (897)	$ 731	$ 1,819	203%

NM = Not meaningful

2021 versus 2020

Interest income for the year ended December 31, 2021 decreased, as compared to the same period in 2020, primarily due to lower yields on our marketable securities portfolio. Interest expense for the year ended December 31, 2021 decreased, as compared to the same period in 2020, due to the repayment of our long-term debt in May 2021, replaced by the issuance of Convertible Notes in May 2021 at a lower effective interest rate. In connection with the repayment of our long-term debt, we recorded a one-time loss on debt extinguishment of $5.2 million in the second quarter of 2021. The change in the fair value of warrant liability is primarily due to the increase in our stock price during the year ended December 31, 2021. The change in other is primarily due to foreign currency transactions and related fluctuations in the value of the Euro compared to the U.S. dollar.

Income Taxes

Our income tax expense and effective income tax rate were as follows (in thousands, except for percentages):

	Year Ended December 31,			Increase (Decrease) from 2020 to 2021	
	2021	2020	2019	$	%
Income tax expense	$ 808	$ -	$ -	$ 808	NM
Effective income tax rate	1.0%	0%	0%	1.0%	NM

2021 versus 2020

We recorded income tax expense of $0.8 million for the year ended December, 31, 2021 resulting from taxable income compared to zero income tax expense in the years ending December 31, 2020 and 2019 where we recorded taxable losses. Our effective tax rate for the year ended December 31, 2021 was 1.03% which is primarily comprised of net operating losses and research and development credits as well as changes in our valuation allowance.

Liquidity and Capital Resources

As of December 31, 2021, we had $546.0 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, 2021, 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.

Advanced payments received from CEPI to reserve a specified quantity of CpG 1018 are initially accounted for as long-term deferred revenue. When we deliver CpG 1018 adjuvant to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the advanced payments from long-term deferred revenue to accrued liabilities. As of December 31, 2021, advance payments totaling $5.4 million were included in other long-term liabilities in our consolidated balance sheets. As of December 31, 2021, advance payments totaling $128.8 million was recorded as CEPI accrual in our consolidated balance sheets.

As of December 31, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.0 million. The Convertible Notes bear interest at a rate of 2.50% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

For the year ended December 31, 2021, we received net cash proceeds of $28.2 million resulting from sales of 2,878,567 shares of our common stock pursuant to a 2020 At Market Sales Agreement with Cowen and Company, LLC (“2020 ATM Agreement”). All of these shares were sold during the three months ended March 31, 2021. As of December 31, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the year ended December 31, 2021, we recorded net income of $76.7 million. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development of our CpG 1018 adjuvant and clinical trials and other development. 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 or future disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. 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.

2021 versus 2020

During the year ended December 31, 2021, we generated $335.5 million of cash from our operations primarily due to our net income of $76.7 million, of which $82.4 million consisted of non-cash items which included change in fair value of warrant liability, stock-based compensation, depreciation and amortization, amortization of right-of-use assets, inventory write-off, non-cash interest expense and accretion and amortization on marketable securities. By comparison, 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. Cash provided by our operations during 2021 increased by $427.8 million. For the year ended December 31, 2021, we received advance payments from collaboration partners totaling $371.9 million to manufacture and supply CpG 1018 adjuvant for delivery in future dates. We classified such payments as deferred revenue until we satisfy our performance obligation to transfer control of CpG 1018 adjuvant to collaboration partners. We invested approximately $130.2 million in prepaid manufacturing. We expect prepaid manufacturing to be converted into CpG 1018 adjuvant inventory within the next twelve months. Net cash provided by 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, 2021, net cash provided by investing activities was $14.2 million compared to $26.5 million of cash used in investing activities for the year ended December 31, 2020. Cash provided by investing activities during the year ended December 31, 2021 included $22.7 million of net proceeds from maturities of marketable securities during 2021 compared to $22.3 million of net purchases of marketable securities during 2020. During the year ended December 31, 2020, we paid $7.0 million of sublicense payment to Merck. In addition, during the year ended December 31, 2021 and 2020, we received $1 million and $6.9 million, respectively, from sale of SD-101 assets, net of transaction costs. Cash used in net purchases of property plant and equipment increased by $5.4 million during the year ended December 31, 2021 compared to the same period in 2020. The increase was, primarily, due to the ongoing manufacturing facility expansion project in Düsseldorf during the year ended December 31, 2021.

During the year ended December 31, 2021 and 2020, net cash provided by financing activities was $55.8 million and $109.5 million, respectively. Cash provided by financing activities for the year ended December 31, 2021 included net proceeds of $219.8 million from the issuance of our Convertible Notes, $28.2 million from our 2020 ATM Agreement, $17.8 million from warrants exercised, $7.4 million from options exercised and employee stock purchase plan, offset by $190.2 million repayment of our long-term debt and $27.2 million purchases of capped call options. Cash provided by financing activities for the year ended December 31, 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.

Contractual Obligations

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, 2021, we are obligated to make lease payments totaling $0.6 million within the next 12 months, plus any operating expenses and taxes.

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, 2021, we are obligated to make lease payments totaling $4.7 million within the next 12 months and $44.3 million beyond the next 12 months, 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.

In September 2021, we entered into a commercial lease agreement in Düsseldorf, Germany (the "New Düsseldorf Lease"). The New Düsseldorf Lease is for the same space that we currently lease in Düsseldorf, Germany and with the same landlord. Our existing lease will continue until December 31, 2021, at which point the New Düsseldorf Lease will be in effect. As of December 31, 2021, we are obligated to make lease payments totaling $0.5 million within the next 12 months and $7.3 million beyond the next 12 months, plus any operating expenses and taxes over the lease term.

In May 2021, we issued $200.0 million aggregate principal amount of 2.50% convertible senior notes due 2026 in a private placement. The purchasers also partially exercised their option to purchase additional Convertible Notes in May 2021 and we issued an additional $25.5 million of the Convertible Notes. As of December 31, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.0 million. The Convertible Notes bear interest at a rate of 2.50% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

In May 2021, we repaid the principal on the term loans (the "Term Loans") under the term loan agreement (“Loan Agreement”) with CRG Servicing LLC in full. With the full repayment of the Term Loans, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

In November 2013, we entered into a Commercial Manufacturing and Supply Agreement with Baxter Pharmaceutical Solutions LLC (“Baxter”) that was amended in September 2021 (as amended, the “Baxter Agreement”). Baxter provides formulation, fill and finish services and produces pre-filled syringes (“PFS”) of HEPLISAV-B for commercial use. Pursuant to the Baxter Agreement, we are obligated to purchase an annual minimum number of batches of PFS for each of the next five calendar years, and there are certain limits on the number of batches that Baxter is required to produce. As of December 31, 2021, our aggregate minimum commitment under the Baxter Agreement was $3.2 million within the next 12 months and $43.4 million beyond the next 12 months, which is included in the material non-cancelable purchase commitments below.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B and CpG 1018 adjuvant. As of December 31, 2021, our material non-cancelable purchase commitments, for the supply of HEPLISAV-B and CpG 1018 adjuvant totaled $52.1 million within the next 12 months.

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

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

In conjunction with 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. 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 and $0.5 million in September 2021. No liability has been recorded under this agreement as of December 31, 2021.

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, 2021 was a $2.3 million loss primarily related to the translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2021, 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, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 28, 2022 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 Matter

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, 2021, the Company's net product revenues for HEPLISAV-B were $61.9 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 HEPLISAV-B 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 28, 2022

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 436,189	$ 32,073
Marketable securities available-for-sale	109,761	132,963
Accounts receivables, net	116,216	22,305
Other receivables	15,600	356
Inventories, net	61,335	63,689
Prepaid manufacturing	159,655	29,423
Prepaid expenses and other current assets	73,764	9,206
Total current assets	972,520	290,015
Property and equipment, net	35,020	30,567
Operating lease right-of-use assets	25,964	26,583
Goodwill	2,125	2,297
Restricted cash	219	237
Other assets	3,398	3,573
Total assets	$ 1,039,246	$ 353,272
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,600	$ 3,312
Accrued research and development	4,688	2,805
CEPI accrual (see Note 9)	128,848	-
Accrued liabilities (see Note 7)	49,796	19,099
Warrant liability	18,016	10,736
Deferred revenue	349,864	38,212
Other current liabilities	2,590	3,247
Total current liabilities	556,402	77,411
Long-term debt, net of debt discount of $1,094 at December 31, 2020	-	179,811
Convertible Notes, net of debt discount of $5,010 at December 31, 2021 (see Note 10)	220,490	-
Long-term portion of lease liabilities	34,316	34,789
Other long-term liabilities	5,664	2,568
Total liabilities	816,872	294,579
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value	-	-
Authorized: 5,000 shares; Issued and outstanding:		
Series B Convertible Preferred Stock — no shares and 4 shares at December 31, 2021 and 2020, respectively		-
Common stock: $0.001 par value; 278,000 shares authorized at December 31, 2021 and 2020; 122,945 shares and 110,190 shares issued and outstanding at December 31, 2021 and 2020, respectively	123	110
Additional paid-in capital	1,441,868	1,352,374
Accumulated other comprehensive (loss) gain	(2,266)	273
Accumulated deficit	(1,217,351)	(1,294,064)
Total stockholders' equity	222,374	58,693
Total liabilities and stockholders' equity	$ 1,039,246	$ 353,272

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenues:			
Product revenue, net	$ 437,099	$ 39,307	$ 34,644
Other revenue	2,343	7,244	575
Total revenues	439,442	46,551	35,219
Operating expenses:			
Cost of sales - product	173,572	11,410	10,172
Cost of sales - amortization of intangible assets	-	2,500	9,217
Research and development	32,228	28,607	62,331
Selling, general and administrative	100,156	79,256	74,986
Gain on sale of assets (Note 8)	(1,000)	(6,851)	-
Restructuring	-	-	13,356
Total operating expenses	304,956	114,922	170,062
Income (loss) from operations	134,486	(68,371)	(134,843)
Other income (expense):			
Interest income	140	1,260	3,370
Interest expense	(11,176)	(19,062)	(16,977)
Sublease income	7,735	7,706	2,619
Loss on debt extinguishment (Note 11)	(5,232)	-	-
Change in fair value of warrant liability (Note 14)	(49,354)	4,124	(7,500)
Other	922	(897)	731
Income (loss) before income taxes	77,521	(75,240)	(152,600)
Provision for income taxes	(808)	-	-
Net income (loss)	76,713	(75,240)	(152,600)
Undistributed earnings allocated to participating securities	(4,569)	-	-
Preferred stock deemed dividend	-	-	(3,267)
Net income (loss) allocable to common stockholders	$ 72,144	$ (75,240)	$ (155,867)
Net income (loss) per share allocable to common stockholders			
Basic	$ 0.62	$ (0.75)	$ (2.16)
Diluted	$ 0.57	$ (0.78)	$ (2.16)
Weighted-average shares used in computing net income (loss) per share allocable to common stockholders:			
Basic	116,264	100,753	72,024
Diluted	133,006	101,504	72,024

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Net income (loss)	$ 76,713	$ (75,240)	$ (152,600)
Other comprehensive (loss) income, net of tax:			
Reclassification of realized gain on available-for-sale securities recognized in interest income	-	(21)	-
Change in unrealized gain on marketable securities available-for-sale	(30)	(20)	140
Cumulative foreign currency translation adjustments	(2,509)	2,701	(512)
Total other comprehensive (loss) income	(2,539)	2,660	(372)
Total comprehensive income (loss)	$ 74,174	$ (72,580)	$ (152,972)

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, 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
Conversion of preferred stock	4,140	4	(4)	-	(4)	-	-	-
Issuance of common stock upon exercise of stock options and restricted stock awards, net	1,560	2	-	-	6,575	-	-	6,577
Issuance of common stock under Employee Stock Purchase Plan	217	-	-	-	841	-	-	841
Issuance of common stock upon exercise of warrants	3,959	4	-	-	59,884	-	-	59,888
Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (see Note 14)	2,879	3	-	-	28,153	-	-	28,156
Issuance of capped call options (see Note 10)	-	-	-	-	(27,240)	-	-	(27,240)
Stock compensation expense	-	-	-	-	21,285	-	-	21,285
Total other comprehensive loss	-	-	-	-	-	(2,539)	-	(2,539)
Net income	-	-	-	-	-	-	76,713	76,713
Balances at December 31, 2021	122,945	$ 123	-	$ -	$ 1,441,868	$ (2,266)	$ (1,217,351)	$ 222,374

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Operating activities			
Net income (loss)	$ 76,713	$ (75,240)	$ (152,600)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	4,296	4,273	8,938
Amortization of right-of-use assets	2,715	2,562	3,375
Inventory write-off	2,588	-	-
Loss (gain) on disposal of property and equipment and from lease termination	47	(98)	18
Amortization of premiums (accretion of discounts) on marketable securities	470	535	(1,462)
Realized gain on available-for-sale securities	-	(57)	-
Loss on debt extinguishment	5,232	-	-
Change in fair value of warrant liability	49,354	(4,124)	7,500
Stock compensation expense	21,285	13,484	25,456
Cost of sales - amortization of intangible assets	-	2,500	9,217
Non-cash interest expense	1,608	2,542	4,973
Tenant improvements provided by the landlord	-	1,137	6,999
Gain on sale of assets	(1,000)	(6,851)	-
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(109,155)	(13,775)	(5,182)
Inventories, net	(234)	(22,357)	(22,310)
Prepaid manufacturing	(130,232)	(29,423)	-
Prepaid expenses and other current assets	(64,558)	(1,826)	(1,278)
Other assets	175	(229)	1,632
Accounts payable	(767)	(3,448)	4,848
CEPI accrual (see Note 9)	128,848	-	-
Lease liabilities	(3,234)	(2,872)	(2,000)
Deferred revenue	311,652	38,212	-
Accrued and other liabilities	39,725	2,804	(9,376)
Net cash provided by (used in) operating activities	335,528	(92,251)	(121,252)
Investing activities			
Acquisition of technology licenses	-	(7,000)	(7,000)
Purchases of marketable securities	(164,928)	(201,786)	(215,191)
Proceeds from maturities and redemptions of marketable securities	187,630	148,565	201,810
Proceeds from sales of marketable securities	-	30,910	-
Purchases of property and equipment, net	(9,477)	(4,072)	(22,401)
Proceeds from sale of assets, net of transaction costs	1,000	6,851	-
Net cash provided by (used in) investing activities	14,225	(26,532)	(42,782)
Financing activities			
Proceeds from long-term debt, net	-	-	74,250
Proceeds from issuances of common stock, net	28,156	108,538	65,948
Proceeds from issuances of preferred stock, net	-	-	13,586
Proceeds from issuance of Convertible Notes, net	219,822	-	-
Purchases of capped call options	(27,240)	-	-
Repayment of long-term debt	(190,194)	-	-
Proceeds from warrants exercises	17,814	-	-
Proceeds from exercise of stock options and restricted stock awards, net	6,577	289	2
Proceeds from Employee Stock Purchase Plan	841	672	565
Net cash provided by financing activities	55,776	109,499	154,351
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1,431)	1,494	(184)
Net increase (decrease) in cash, cash equivalents and restricted cash	404,098	(7,790)	(9,867)
Cash, cash equivalents and restricted cash at beginning of year	32,310	40,100	49,967
Cash, cash equivalents and restricted cash at end of year	$ 436,408	$ 32,310	$ 40,100
Supplemental disclosure of cash flow information			
Cash paid during the year for income taxes	$ 1,312	$ -	$ -
Cash paid during the year for interest	$ 9,815	$ 16,541	$ 12,147
Non-cash investing and financing activities:			
Purchases of property and equipment, not yet paid	$ 591	$ 361	$ 2,698
Proceeds allocated to warrant liability at issuance	$ -	$ -	$ 7,360
Right-of-use assets obtained in exchange for operating lease liabilities	$ 2,468	$ -	$ 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 innovative vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and European Union 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, plague, Tdap, seasonal influenza, universal influenza and shingles. 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 innovative vaccines.

Liquidity and Financial Condition

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $546.0 million. In May 2021, we issued $225.5 million in 2.50% convertible senior notes due 2026 (“Convertible Notes”). We used approximately $190.2 million of the net proceeds to retire our previous loan agreement with CRG Servicing LLC ("Loan Agreement") (see Note 11) and $27.2 million of the net proceeds to pay the costs of the capped call transactions (the “Capped Calls”) (see Note 10). As of December 31, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.0 million (see Note 10). The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the year ended December 31, 2021, we recorded net income of $76.7 million. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development and procurement of our CpG 1018 adjuvant, and clinical trials and other development. 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, 2021, 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. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent or future disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. 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, 2021 and 2020, the cumulative translation adjustments balance was $(2.3) million and $0.2 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, 2021, 2020 and 2019, we reported an unrealized (loss) gain of $(2.5) million, $2.7 million and $(0.5) 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, 2021, 2020 and 2019, we reported a gain (loss) of $0.9 million, $(0.8) million and $0.2 million, respectively, resulting from currency transactions in our consolidated statements of operations.

Cash, Cash Equivalents and Marketable Securities

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

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

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

Our accounts receivable balance consists, primarily, of amounts due from product sales. Accounts receivable are recorded net of reserves for chargebacks, distribution fees, trade discounts and doubtful accounts. 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. As of December 31, 2021 and 2020, three customers collectively represented approximately 76% and 86% of our HEPLISAV-B trade receivable balance, respectively. As of December 31, 2021 and 2020, one customer represented approximately 94% and 100% of our CpG 1018 trade receivable balance, respectively.

Our product candidates will require approval from the United States Food and Drug Administration ("FDA") and foreign regulatory agencies before commercial sales can commence. There can be no assurance that our products will receive any of these required approvals. The denial or delay of such approvals 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.

As of December 31, 2021 and 2020, 43% and 57%, respectively, of our long-lived assets were located in the United States and the remaining long-lived assets were located in Germany.

Inventories, net

HEPLISAV-B Inventories, net

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. Additionally, for the year ended December 31, 2021, due to the COVID-19 pandemic and its prolonged impact on vaccine utilization and corresponding revisions to our sales forecast, we recorded an approximately $2.6 million write-off to cost of sales – product associated with HEPLISAV-B slow moving short-dated inventory that had been manufactured prior to the beginning of the COVID-19 pandemic. For the year ended December 31, 2020 and 2019, there were no inventory write-offs recognized.

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

CpG 1018 Inventories, net

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete

inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the year ended December 31, 2021 and 2020, there were no inventory reserves recognized.

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 in connection with our restructuring. See Note 17. There was no accelerated depreciation recorded during the year ended December 31, 2021 and 2020.

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.

Convertible Notes

We accounted for the Convertible Notes (see Note 10) as a long-term liability equal to the proceeds received from issuance, including the embedded conversion feature, net of the unamortized debt issuance and offering costs on the consolidated balance sheets. We evaluate all conversion, repurchase and redemption features contained in a debt instrument to determine if there are any embedded features that require bifurcation as a derivative. The conversion feature is not required to be accounted for separately as an embedded derivative. We amortize debt issuance and offering costs over the contractual term of the Convertible Notes, using the effective interest method, as interest expense on the consolidated statements of operations.

Capped Calls

We evaluate financial instruments under ASC 815. In May 2021, in connection with the issuance of the Convertible Notes, we entered into the Capped Calls (see Note 10). The Capped Calls cover the same number of shares of common stock that initially underlie the Convertible Notes (subject to anti-dilution and certain other adjustments). The Capped Calls meet the definition of derivative under ASC 815. In addition, the Capped Calls meet the conditions in ASC 815 to be classified in stockholders' equity and are not subsequently remeasured as long as the conditions for the equity classification continue to be met.

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. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

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.

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 and other relevant factors.

There were no material adjustments to these estimates for the years ended December 31, 2021 and 2019. 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.

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. Since our performance obligation is part of a

contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

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.

Other Revenue

Other revenue includes grant, collaboration and manufacturing service revenue. We have entered into grant agreements, 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.

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 ("RSUs") and stock options is estimated at the grant date based on the award’s estimated fair value.

For awards that vest based on service conditions and market conditions, the Company uses a straight-line method to recognize compensation expense over the award’s requisite service period, assuming estimated forfeiture rates. For awards that contain performance conditions, the Company determines the appropriate amount to expense at each reporting date based on the anticipated achievement of performance targets, which requires judgement, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, the Company records a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, the Company re-assesses the estimated performance and updates the number of performance-based awards that it believes will ultimately vest.

Fair value of restricted stock units is determined at the date of grant using the Company’s closing stock price, with the exception of performance-based RSUs with market conditions, which are measured using the Monte Carlo simulation method on the date of grant. 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, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations.

Based on all available evidence, both positive and negative, and the weight of that evidence to the extent such evidence can be objectively verified, we believe that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more likely than not to be realized and, accordingly, we have determined a need for a full valuation allowance. Given our current earnings, we believe that, within the next twelve months, sufficient positive evidence may become available to allow us to reach a conclusion that a portion of the valuation allowance recorded against the deferred tax assets held may be reversed. A reversal would result in an income tax benefit for the quarterly and annual fiscal period in which we determine to release the valuation allowance. However, the exact timing and amount of a valuation allowance release are subject to change on the basis of the level of profitability that we actually achieve.

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 2019-12

In December 2019, the FASB issued Accounting Standards Update ("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

We adopted 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 on January 1, 2021 using the modified retrospective method. This ASU simplifies the accounting for convertible instruments and requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. Entities also need to recombine instruments that were previously separated into two units of account if separation is no longer required. The adoption of this ASU did not have a material impact on our consolidated financial statements as there were no outstanding financial instruments that require recombination at January 1, 2021.

Accounting Standards Update 2016-13

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments. The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. 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.

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, 2021 and 2020.

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, 2021				
Assets				
Money market funds	$ 429,194	$ -	$ -	$ 429,194
U.S. treasuries	-	4,004	-	4,004
U.S. government agency securities	-	26,548	-	26,548
Corporate debt securities	-	79,209	-	79,209
Total assets	$ 429,194	$ 109,761	$ -	$ 538,955
Liabilities				
Warrant liability	$ -	$ -	$ 18,016	$ 18,016

	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

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, 2021, we used the following key assumptions to estimate the fair value of warrant liability:

Number of shares	1,882,600
Expected term	0.1 years
Expected volatility	0.7
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, 2021 and 2020 (in thousands):

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
Decrease in fair value of warrants exercised	(4,765)
Warrants exercised	(42,074)
Increase in the estimated fair value of warrant liability upon revaluation	54,119
Balance at December 31, 2021	$ 18,016

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		
	2021	2020	2019
Cash and cash equivalents	$ 436,189	$ 32,073	$ 39,884
Restricted cash	219	237	216
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 436,408	$ 32,310	$ 40,100

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 8.

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2021				
Cash and cash equivalents:				
Cash	$ 6,995	$ -	$ -	$ 6,995
Money market funds	429,194	-	-	429,194
Total cash and cash equivalents	436,189	-	-	436,189
Marketable securities available-for-sale:				
U.S. treasuries	4,005	-	(1)	4,004
U.S. government agency securities	26,555	-	(7)	26,548
Corporate debt securities	79,200	9	-	79,209
Total marketable securities available-for-sale	109,760	9	(8)	109,761
Total cash, cash equivalents and marketable securities	$ 545,949	$ 9	$ (8)	$ 545,950
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

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

.

	December 31, 2021	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 109,760	$ 109,761
Mature after one year through two years	-	-
	$ 109,760	$ 109,761

There were no gross realized gains or losses on investments for each of the year ended December 31, 2021 and 2019. For the year ended December 31, 2020, there were gross realized gains on investments of $0.1 million and no gross realized losses. Realized gains are included in interest income in the consolidated statements of operations. All investments with unrealized losses at December 31, 2021 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	
	2021	2020
Raw materials	$ 26,637	$ 25,121
Work-in-process	14,748	30,293
Finished goods	19,950	8,275
Total	$ 61,335	$ 63,689

As of December 31, 2021 and 2020, included in finished goods inventory was $18.6 million and $8.3 million of HEPLISAV-B inventory, respectively. The remaining balance in finished goods inventory was CpG 1018 adjuvant. There was no CpG 1018 adjuvant within raw materials and work-in-process inventory balance as of December 31, 2021 and 2020. Additionally, for the year ended December 31, 2021, due to the COVID-19 pandemic and its prolonged impact on vaccine utilization and corresponding revisions to our sales forecast, we recorded an approximately $2.6 million write-off to cost of sales – product associated with HEPLISAV-B slow moving short-dated inventory that had been manufactured prior to the beginning of the COVID-19 pandemic. For the year ended December 31, 2020 and 2019, there were no inventory write-offs recognized.

We recorded prepaid manufacturing costs related to prepayments made to third-party manufacturers of CpG 1018 adjuvant, of $159.7 million and $29.4 million as of December 31, 2021 and 2020, respectively. We expect these costs to be converted into inventory within the next twelve months.

6. Property and Equipment, net

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

	Estimated Useful Life (In years)	December 31, 2021	December 31, 2020
Manufacturing equipment	5-13	$ 12,532	$ 13,884
Lab equipment	5-13	2,492	2,888
Computer equipment	3	5,336	5,255
Furniture and fixtures	3-13	2,463	2,510
Leasehold improvements	2-10	27,634	28,417
Assets in progress		9,941	1,024
		60,398	53,978
Less accumulated depreciation and amortization		(25,378)	(23,411)
Total		$ 35,020	$ 30,567

Depreciation and amortization expense on property and equipment was $4.3 million, $4.3 million and $8.9 million for the years ended December 31, 2021, 2020 and 2019, 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.

7. Current Accrued Liabilities and Accrued Research and Development

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

	December 31, 2021	December 31, 2020
Payroll and related expenses	$ 13,011	$ 8,684
Revenue reserve accruals	8,253	6,040
Accrued inventory	20,868	338
Other accrued liabilities	7,664	4,037
Total	$ 49,796	$ 19,099

8. 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”). 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.

In September 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 have received tenant improvement allowance totaling $8.1 million through December 31, 2021. 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, 2021 and 2020 consolidated balance sheets primarily relate to the Horton Street Master Lease. Lease expense related to the Horton Street Master Lease is included in operating expense in our consolidated statements of operations.

In connection with the organizational restructuring in May 2019, 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 term is 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, 2021, 2020 and 2019, we recognized $7.7 million, $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.

In September 2021, we entered into a commercial lease agreement in Düsseldorf, Germany (the "New Düsseldorf Lease"). The New Düsseldorf Lease is for the same space that we currently lease in Düsseldorf, Germany and with the same landlord. Our existing lease will continue until December 31, 2021, at which point the New Düsseldorf Lease will be in effect. We have determined that the New Düsseldorf Lease qualifies as a modification not accounted for as a separate contract. The New Düsseldorf Lease has an initial term of 10 years, beginning on January 1, 2022, 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 assets and liabilities as we did not consider it reasonably certain that we would exercise the options. Beginning on January 1, 2024, the base rent is subject to an annual increase at the same percentage of Consumer Price Index of Germany. We are also responsible for certain operating expenses and taxes throughout the life of the New Düsseldorf Lease. We used our estimated incremental borrowing rate of 10.1% to recognize the initial right-of-use asset for the New Düsseldorf Lease.

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

	Year Ended December 31,		
	2021	2020	2019
Operating lease expense	$ 6,265	$ 6,267	$ 6,886

Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2021 and 2020 was $7.0 million and $6.9 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, 2021	December 31, 2020
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 2,577	$ 3,247
Long-term portion of lease liabilities	34,316	34,789
Total operating lease liabilities	$ 36,893	$ 38,036

At December 31, 2021, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2022	$ 5,357	$ 6,174
2023	5,518	5,634
2024	5,684	5,778
2025	5,854	5,927
2026	6,030	6,080
Thereafter	27,712	28,259
Total	$ 56,155	57,852
Less:		
Present value adjustment		(20,959)
Total		$ 36,893

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

	December 31, 2021	December 31, 2020
Weighted average remaining lease term	9.1 years	9.1 years
Weighted average discount rate	10.1%	10.1%

Commitments

As of December 31, 2021, our purchase commitments include non-cancelable purchase for the supply of HEPLISAV-B and CpG 1018 adjuvant. The following summarizes our material purchase commitments at December 31, 2021 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Years ending December 31,	(in thousands)
2022	$ 55,318
2023	9,312
2024	10,857
2025	11,367
2026	11,872
Thereafter	-
Total	98,726

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, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.0 million (see Note 10). The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

During 2004, we 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, 2021 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, 2021 and 2020.

Sale of SD-101 Program

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 September 2021, we received payment of $1 million from TriSalus for their meeting a pre-commercialization milestone.

For the year ended December 31, 2021 and 2020, we recognized a gain on sale of SD-101 assets of $1 million and $6.9 million, respectively based on the amount of consideration received, net of any transaction costs.

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. Pursuant to this agreement, we paid Holdings $0.5 million in September 2021 and $2.5 million in August 2020 which were included in selling, general and administrative expense in our consolidated statements of operations for the year ended December 31, 2021 and 2020, respectively.

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.

9. 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. 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.

In January 2021, we entered into an agreement (the "CEPI Agreement") with CEPI for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant ("CpG 1018 Materials"). The CEPI Agreement enables CEPI to direct the supply of CpG 1018 Materials to CEPI partners. CEPI partner(s) would purchase CpG 1018 Materials under separately negotiated agreements. The CEPI Agreement also allows us to sell CpG 1018 Materials to third parties if not purchased by a CEPI partner within a two-year term.

In exchange for reserving CpG 1018 Materials and agreeing to sell CpG 1018 Materials to CEPI partner(s) at pre-negotiated prices, CEPI agreed to provide payments in the form of an interest-free, unsecured, forgivable loan (the "Advance Payments") of up to $99.0 million. We are obligated to repay the Advance Payments, in proportion to quantity sold, if and to the extent we receive payments from sales of CpG 1018 Materials reserved under the CEPI 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 CEPI Agreement, the applicable Advance Payments will be forgiven at the end of the two-year term.

In May 2021, we entered into the first Amendment to the CEPI Agreement. This Amendment provided for the manufacture and reservation of an additional specified quantity of CpG 1018 adjuvant. In exchange for reserving an additional specified quantity of CpG 1018 adjuvant, CEPI agreed to provide additional Advance Payments of up to $77.4 million, together with the initial CEPI Agreement, for total Advance Payments of up to $176.4 million.

We determined that the accounting of the Advance Payments is under the scope of ASC 606. The Advance Payments are to cover the costs of manufacture and to reserve CpG 1018 Materials, which is an output of our ordinary activities. As such, the Advance Payments are initially classified as long-term deferred revenue in our consolidated balance sheets. We are obligated to repay CEPI, in proportion to quantity sold and within a certain period, upon receipt of payment from CEPI partner(s). Thus, when we deliver CpG 1018 Materials to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the Advanced Payments from long-term deferred revenue to accrued liabilities. We recognize the Advance Payments as revenue when the amount (or a portion thereof) is forgiven by CEPI when (i) the CpG 1018 Materials are not sold through to CEPI partner(s), (ii) there is no alternative use and (iii) the CpG 1018 Materials are destroyed.

Through December 31, 2021, we have received Advance Payments totaling approximately $168.5 million pursuant to the CEPI Agreement. As of December 31, 2021, advance payments totaling $5.4 million were included in other long-term liabilities and $128.8 million were recorded as CEPI accrual in our consolidated balance sheets. As of December 31, 2021, we recorded $14.6 million in CEPI receivable which is included in other receivables in our consolidated balance sheets. There were no such balances recorded in our consolidated balance sheets as of December 31, 2020.

Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc.

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with Clover's COVID-19 vaccine candidate, SCB-2019 (the "Clover Supply Agreement"). Under the Clover Supply Agreement, Clover has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Clover's commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant ("Clover Product"). The Clover Supply Agreement also provides terms for Clover to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI.

Pricing for CpG 1018 adjuvant is variable depending on the destination where Clover ultimately sells Clover Product to. Pursuant to the Clover Supply Agreement, our initial invoicing is at the lowest price tier, with a true-up mechanism to issue additional invoice for the difference between the initial invoice price and the higher tiered price, if any. In addition, if the net selling price of such Clover Product exceeds a threshold specified in the Clover Supply Agreement, we are entitled to a royalty calculated as a percentage of the excess portion of such net selling price.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay the purchase price upon the earliest of (i) the true-up exercise, (ii) within a specified period after Clover delivers Clover Product to a customer, or (iii) Clover's receipt of payment for Clover Product from a customer. For CpG 1018 adjuvant ordered by Clover outside the CEPI Agreement, Clover is obligated to pay a specified percentage of the purchase price, as set forth in a purchase order submitted by Clover, upon our acceptance of such purchase order, and the remainder of the purchase price upon the release of such CpG 1018 adjuvant.

We recognize revenue at the lowest price tier upon transfer of control of CpG 1018 adjuvant to Clover. The potential true-up amount and royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue. When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement, we recognize product revenue and a corresponding contract asset as our right to consideration is contingent on something other than the passage of time, as outlined above.

As of December 31, 2021, our contract asset balance of $62.5 million was included in other current assets in our consolidated balance sheets. As of December 31, 2021, we recorded accounts receivable balance of $2.1 million from Clover. As of December 31, 2021, we recognized approximately $191.1 million in deferred revenue for a portion of Clover's binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement. There was no deferred revenue recognized for a portion of Clover's binding commitment to purchase CpG 1018 adjuvant that was reserved for Clover under the CEPI Agreement. There was no contract asset, accounts receivable or deferred revenue balance at the beginning of the period.

For the year ended December 31, 2021, we recognized CpG 1018 product revenue of $72.2 million from Clover. There was no CpG 1018 product revenue from Clover recognized during the year ended December 31, 2020 and 2019.

Biological E. Limited

In July 2021, we entered into an agreement (the "Bio E Supply Agreement") with Biological E. Limited ("Bio E"), for the commercial supply of CpG 1018 adjuvant, for use with Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™. Under the Bio E Supply Agreement, Bio E has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine ("Bio E Product") with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides terms for Bio E to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI.

Pricing for CpG 1018 adjuvant is variable depending on the destination where Bio E ultimately sells Bio E Product to. Pursuant to the Bio E Supply Agreement, our initial invoicing will be at the lowest price tier, with a true-up mechanism to issue additional invoice for the difference between the initial invoice price and the higher tiered price, if any. In addition, if the net selling price of such Bio E Product exceeds a threshold specified in the Bio E Supply Agreement, we are entitled to a royalty calculated as a percentage of the excess portion of such net selling price.

For CpG 1018 adjuvant reserved for Bio E under the CEPI Agreement, Bio E is obligated to pay, in full, the aggregate purchase price, as set forth in a purchase order submitted by Bio E, upon delivery of CpG 1018 adjuvant. For CpG 1018 adjuvant ordered by Bio E outside the CEPI Agreement, Bio E is obligated to pay a specified percentage of the purchase price, as set forth in a purchase order submitted by Bio E, upon our acceptance of such purchase order, and the remainder of the purchase price upon the delivery of such CpG 1018 adjuvant.

We recognize revenue at the lowest price tier upon transfer of control of CpG 1018 adjuvant to Bio E. The potential true-up amount and royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue.

As of December 31, 2021, we recorded accounts receivable balance of $96.1 million from Bio E. As of December 31, 2021, we recognized approximately $103.3 million in deferred revenue for a portion of Bio E's binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement. There was no deferred revenue recognized for a portion of Bio E's binding commitment to purchase CpG 1018 adjuvant that was reserved for Bio E under the CEPI Agreement. There was no accounts receivable or deferred revenue balance at the beginning of the period.

For the year ended December 31, 2021, we recognized CpG 1018 product revenue of $185.7 million from Bio E. There was no CpG 1018 product revenue from Bio E recognized during the year ended December 31, 2020 and 2019.

Medigen Vaccine Biologics

In February 2021, we entered into a Supply Agreement ("Medigen Supply Agreement") with Medigen Vaccine Biologics ("Medigen") to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen's COVID-19 vaccine for delivery in the first and second quarters of 2021.

In August 2021, we entered into a second supply agreement ("Medigen Supply Agreement No. 2") to manufacture and supply additional specified quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021.

Under Medigen Supply Agreement No. 2, pricing for CpG 1018 adjuvant is variable depending on the destination where Medigen ultimately sells Medigen Product to. Pursuant to the Medigen Supply Agreement No. 2, we invoice Medigen based on the highest-tier price, with a true-up mechanism to issue credit to Medigen for the difference between the initial invoice price and the lower tiered price, if any. We invoice Medigen a specified percentage of the aggregate price of the order upon acceptance of the order and the remaining upon delivery. In addition, we are entitled to a royalty calculated as a percentage of the adjusted net sales.

We recognize revenue upon transfer of control of CpG 1018 adjuvant to Medigen at the highest-tiered price. The potential royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue.

As of December 31, 2021, we recorded accounts receivable balance of $2.4 million from Medigen. There was no accounts receivable balance at the beginning of the period. For the year ended December 31, 2021 and 2020, we recognized CpG 1018 product revenue from Medigen of $26.7 million and $1.2 million, respectively. There was no CpG 1018 product revenue from Medigen recognized during the year ended December 31, 2019.

Valneva SE

In April 2020, we entered into a collaboration agreement ("Valneva Collaboration Agreement") with Valneva Scotland Limited (“Valneva”) to provide CpG 1018 adjuvant for use in the development of Valneva’s COVID-19 vaccine candidate ("VLA2001"). The Valneva Collaboration Agreement was amended in July 2020, to provide additional quantities of CpG 1018 adjuvant. In September 2020, we entered into a supply agreement (“Valneva Supply Agreement”) with Valneva to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the commercialization of VLA2001.

We concluded that the Valneva Collaboration Agreement and the Valneva 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 to provide CpG 1018 adjuvant to Valneva. Therefore, the Valneva Collaboration Agreement and the Valneva Supply Agreement should be combined and accounted for as a single arrangement.

In October 2021, we and Valneva entered into a letter agreement (the “Valneva Amendment”) modifying certain deliverables of the Valneva Supply Agreement. Specifically, the Valneva Amendment modifies the original Valneva Supply Agreement as follows: (1) cancels certain purchase orders for CpG 1018 adjuvant previously issued under the original Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment; and (2) provides a future delivery schedule for commercial supply of CpG 1018 adjuvant through 2022. As of the date of the Valneva Amendment, we had received non-refundable advance payments of approximately $55.4 million associated with the cancelled purchase orders.

In accordance with revenue recognition guidance in ASC 606, the Valneva Amendment was determined to be a contract modification and will be accounted for prospectively as one agreement with consideration allocated to future performance obligations. We have identified one remaining performance obligation which is the delivery of CpG 1018 adjuvant through 2022. The total amount of consideration allocated to the remaining performance obligation includes approximately $55.4 million of advance payments received as of the date of the Valneva Amendment plus additional future consideration to be received in connection with final delivery of product. As of December 31, 2021, approximately $55.4 million of advance payments remain recorded as deferred revenue and will be recognized as product revenue when we satisfy our remaining performance obligation to deliver CpG 1018 adjuvant under the Valneva Amendment.

As of December 31, 2021 and 2020, deferred revenue related to Valneva was $55.4 million and $37.0 million, respectively. For the year ended December 31, 2021 and 2020, we recognized CpG 1018 product revenue of $89.4 million and $2.0 million, respectively. There was no CpG 1018 product revenue from Valneva recognized during the year ended December 31, 2019.

Bill & Melinda Gates Foundation Grant Agreement

In July 2020, we entered into a grant agreement (the "BMGF 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 and we received $1.2 million of the grant from BMGF which we accounted for as deferred revenue in our consolidated balance sheets as of December 31, 2020.

In July 2021, the BMGF Grant Agreement expired. Pursuant to the BMGF Grant Agreement, we were not obligated to return the $1.2 million funding that we spent on grant-related activities. For the year ended December 31, 2021, we recognized $1.2 million as other revenue in our consolidated statements of operations.

U.S. Department of Defense

In September 2021, we entered into an agreement with the U.S. Department of Defense ("DoD") for the development of a recombinant plague vaccine adjuvanted with CpG 1018 for approximately $22.0 million over two and a half years. Under the agreement, we will conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. We anticipate the Phase 2 trial will commence in 2022. For the year ended December 31, 2021, we recognized revenue of $0.5 million which are included in other revenue in our consolidated statements of operations.

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, 2021, 2020 and 2019, we recognized collaboration revenue of $0.4 million, $0.9 million and $0.1 million, respectively which are included in other revenue in our consolidated statements of operations.

10. Convertible Notes

In May 2021, we issued $200.0 million aggregate principal amount of 2.50% convertible senior notes due 2026 in a private placement. The purchasers also partially exercised their option to purchase additional Convertible Notes in May 2021 and we issued an additional $25.5 million of the Convertible Notes. Total proceeds from the issuance of the Convertible Notes, net of debt issuance and offering costs of $5.7 million, were $219.8 million. We used $190.2 million of the net proceeds to repay, in full, our outstanding debt and other obligations under the Loan Agreement (see Note 11) and $27.2 million of the net proceeds to pay the costs of the capped call transactions described below.

The Convertible Notes are general unsecured obligations and accrue interest at a rate of 2.50% per annum payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

The Convertible Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, at an initial conversion rate of 95.5338 shares of our common stock per $1,000 principal amount of the Convertible Notes, which is equivalent to an initial conversion price of approximately $10.47 per share of our common stock. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding February 15, 2026, only under the following circumstances:

1. During any calendar quarter commencing after September 30, 2021 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
2. During the five business day period after any ten consecutive trading day period (the “measurement period”), in which the “trading price” (as defined the indenture governing the Convertible Notes) per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;
3. If we call such Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
4. Upon the occurrence of specified corporate events as set forth in the indenture governing the Convertible Notes.

On or after February 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders of the Convertible Notes may convert all or any portion of their Convertible Notes regardless of the foregoing circumstances. The Convertible Notes were convertible, in whole or in part, at the option of the holders between October 1, 2021 through December 31, 2021 as the conditions allowing holders of the Convertible Notes to convert have been met. None of the Convertible Notes had been converted during this period.

On January 1, 2022, the conditional conversion feature of the Convertible Notes was triggered as the last reported sale price of our common stock was more than or equal to 130% of the conversion price for at least 20 trading days in the period of 30 consecutive trading days ending on December 31, 2021 (the last trading day of the immediately preceding fiscal quarter), and therefore the Convertible Notes are currently convertible, in whole or in part, at the option of the holders between January 1, 2022 through March 31, 2022. Whether the Convertible Notes will be convertible following such period

will depend on the continued satisfaction of this condition or another conversion condition in the future. We had not received any conversion notices. Since we have the election of repaying the Convertible Notes in cash, shares of our common stock, or a combination of both, we continued to classify the Convertible Notes as long-term debt on the consolidated balance sheets as of December 31, 2021.

We may redeem for cash all or any portion of the Convertible Notes, at our option, on or after May 20, 2024 and prior to the 31st scheduled trading day immediately preceding the maturity date, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on the trading day immediately preceding the date on which we provide notice of redemption, at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If we undergo a fundamental change (as set forth in the indenture governing the Convertible Notes), noteholders may require us to repurchase for cash all or any portion of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to the fundamental change repurchase date. In addition, following certain corporate events (as set forth in the indenture governing the Convertible Notes) or if we deliver a notice of redemption prior to the maturity date, we will, in certain circumstances, adjust the conversion rate for a noteholder who elects to convert its notes in connection with such a corporate event or such notice of redemption.

As a result of adopting ASU 2020-06, we accounted for the Convertible Notes as a single liability. As of December 31, 2021, the Convertible Notes were recorded at the aggregate principal amount of $225.5 million less unamortized issuance costs of $5.0 million as a long-term liability on the consolidated balance sheets. As of December 31, 2021, the fair value of the Convertible Notes was $368.6 million. See Note 2. The debt issuance costs are amortized to interest expense over the contractual term of the Convertible Notes at an effective interest rate of 3.1%.

The following table presents the components of interest expense related to Convertible Notes (in thousands):

	Year Ended December 31, 2021
Stated coupon interest	$ 3,555
Amortization of debt issuance cost	669
Total interest expense	$ 4,224

Capped Calls

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers of the Convertible Notes and other financial institutions, totaling $27.2 million (the “Capped Calls”). The Capped Calls cover, subject to customary adjustments, the number of shares of our common stock that initially underlie the Convertible Notes (or 21,542,871 shares of our common stock). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments. Conditions that cause adjustments to the initial strike price of the Capped Calls mirror conditions that result in corresponding adjustments to the conversion price of the Convertible Notes. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

For accounting purposes, the Capped Calls are considered separate financial instruments and not part of the Convertible Notes. As the Capped Calls transactions meet certain accounting criteria, we recorded the cost of the Capped Calls, totaling $27.2 million, as a reduction to additional paid-in capital within the consolidated statements of stockholders’ equity.

11. Long-Term Debt

Long-Term Debt

On February 20, 2018, we entered into a $175.0 million term 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”). Net proceeds under the Loan Agreement were $173.3 million. The Term Loans under the Loan Agreement bore interest at a rate equal to 9.5% per annum. The Term Loans had a maturity date of December 31, 2023.

In May 2021, we repaid the principal on the Term Loans, in full, using the net proceeds from the Convertible Notes issuance. In connection with the early repayment of the Term Loans, in the second quarter of 2021, we recorded $5.2 million loss on debt extinguishment related to the amount we paid to terminate the Term Loans in excess of its carrying value at the time of the repayment. Our final payment of $190.2 million to CRG Servicing LLC satisfied all of our obligations under the Loan Agreement. With the full repayment of the Term Loans, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

We recorded $7.0 million, $19.1 million and $16.5 million of interest expense related to the Term Loans during the year ended December 31, 2021, 2020 and 2019, respectively.

12. Revenue Recognition

Disaggregation of Revenues

The following table disaggregates our product revenue, net by product and geographic region and disaggregates our other revenues by geographic region (in thousands):

	Year Ended December 31, 2021			Year Ended December 31, 2020			Year Ended December 31, 2019		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net									
HEPLISAV-B	$ 61,870	$ -	$ 61,870	$ 36,030	$ -	$ 36,030	$ 34,644	$ -	$ 34,644
CpG 1018	-	375,229	375,229	-	3,277	3,277	-	-	-
Total product revenue, net	$ 61,870	$ 375,229	$ 437,099	$ 36,030	$ 3,277	$ 39,307	$ 34,644	$ -	$ 34,644
Other revenue	1,915	428	2,343	-	7,244	7,244	410	165	575
Total revenues	$ 63,785	$ 375,657	$ 439,442	$ 36,030	$ 10,521	$ 46,551	$ 35,054	$ 165	$ 35,219

Revenues from Major Customers

The following table summarizes HEPLISAV-B product revenue from each of our three largest Customers (as a percentage of total HEPLISAV-B product revenue):

	Year Ended December 31,		
	2021	2020	2019
Largest Customer	21%	21%	22%
Second largest Customer	19%	20%	21%
Third largest Customer	19%	20%	19%

The following table summarizes CpG 1018 product revenue from each of our three largest collaboration partners (as a percentage of total CpG 1018 product revenue):

	Year Ended December 31,		
	2021	2020	2019
Largest collaboration partner	49%	62%	0%
Second largest collaboration partner	24%	36%	0%
Third largest collaboration partner	19%	2%	0%

Contract Balances

The following table summarizes balances and activities in HEPLISAV-B product revenue allowance and reserve categories (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, 2021:				
Accounts receivable reserves(1)	$ 2,836	$ 18,209	$ (17,222)	$ 3,823
Revenue reserve accruals(2)	$ 6,040	$ 13,077	$ (10,864)	$ 8,253
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

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

When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement to Clover, we recognize product revenue and a corresponding contract asset as our right to consideration is conditioned on something other than the passage of time. See Note 9 for further discussion. The following table summarizes balances and activities in our contract asset account (in thousands):

	Balance at Beginning of Period	Additions (1)	Subtractions	Balance at End of Period
Year ended December 31, 2021:				
Contract asset	$ -	$ 62,525	$ -	$ 62,525
Year ended December 31, 2020:				
Contract asset	$ -	$ -	$ -	$ -

(1) Additions are revenues recognized for CpG 1018 adjuvant transferred to Clover that is reserved under the CEPI Agreement.

Payments received or invoices issued before we satisfy our performance obligations are recorded as deferred revenue until we satisfy such performance obligations. Our deferred revenue activities are related to CpG 1018 product sales. The following table summarizes balances and activities in our deferred revenue accounts (in thousands):

	Balance at Beginning of Period	Additions (1)	Subtractions (2)	Revenue recognized in the current period included in deferred revenue balance at the beginning of the period	Balance at End of Period
Year ended December 31, 2021:					
Deferred revenue	$ 38,212	$ 371,860	$ (21,996)	$ (38,212)	$ 349,864
Long-term deferred revenue	-	168,467	(163,082)	-	5,385
Year ended December 31, 2020:					
Deferred revenue	$ -	$ 38,212	$ -	$ -	$ 38,212
Long-term deferred revenue	-	-	-	-	-

(1) Additions are primarily payments received or invoices issued before we satisfy our performance obligations.
(2) Subtractions are primarily revenues recognized in the period and reclassification from long-term deferred revenue to CEPI accrual.

13. Net Income (Loss) Per Share

We compute net income (loss) per share of common stock using the two-class method required for participating securities. We consider Series B Preferred Stocks and warrants to be participating securities because holders of such shares have dividend rights in the event of our declaration of a dividend for common shares. Undistributed earnings allocated to participating securities are subtracted from net income (loss) in determining net income (loss) attributable to common stockholders.

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of our common stock outstanding.

For the calculation of diluted net income (loss) per share, net income (loss) attributable to common stockholders for basic net income (loss) per share is adjusted by the effect of dilutive securities, including awards under our equity compensation plans and change in fair value of warrant liability. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the resulting net income (loss) attributable to common stockholders by the weighted-average number of fully diluted common shares outstanding.

	Year Ended December 31,		
	2021	2020	2019
Numerator			
Net income (loss)	$ 76,713	$ (75,240)	$ (152,600)
Less: undistributed earnings allocated to participating securities	(4,569)	-	-
Less: preferred stock deemed dividend	-	-	(3,267)
Net income (loss) allocable to common stockholders, basic	72,144	(75,240)	(155,867)
Add: undistributed earnings allocated to Series B and warrants	4,569	-	-
Less: undistributed earnings allocated to Series B and warrants	(4,190)	-	-
Add: interest expense on convertible notes	3,168	-	-
Less: removal of change in fair value of warrant liability	-	(4,124)	-
Net income (loss) allocable to common stockholders, diluted	$ 75,691	$ (79,364)	$ (155,867)
Denominator			
Weighted average shares used to compute net income (loss) allocable to common stockholders per share, basic	116,264	100,753	72,024
Effect of dilutive shares:			
Stock-based compensation plans	3,075	-	-
Convertible Notes (as converted to common stock)	13,667	-	-
Effect of dilutive warrants	-	751	-
Weighted average shares used to compute net income (loss) allocable to common stockholders per share, diluted	133,006	101,504	72,024

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

	December 31,		
	2021	2020	2019
Outstanding securities not included in diluted net income (loss) allocable to common stockholders per share calculation (in thousands):			
Stock options and stock awards	5,953	10,299	9,789
Series B Convertible Preferred Stock (as converted to common stock)	-	4,140	4,840
Warrants (as exercisable into common stock)	1,883	-	5,841
Convertible Notes (as converted to common stock)	-	-	-

14. Common Stock

Common Stock Outstanding

As of December 31, 2021, there were 122,945,357 shares of our common stock outstanding.

In August 2019, we sold 18,525,000 shares of our common stock, par value $0.001 per share, 4,840 shares of our Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred Stock") and warrants to purchase up to an aggregate of 5,841,250 shares of our common stock in an underwritten public offering (the "Offering") for aggregate net proceeds of approximately $65.6 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 the Offering on the same terms as the other investors in the Offering. Following the Offering, Andrew A. F. Hack, M.D., Ph.D., a Managing Director of Bain Capital Life Sciences, was appointed to our board of directors.

In June 2021, Bain Capital Life Sciences and its affiliates sold warrants to purchase an aggregate of 2,916,250 shares of our common stock for aggregate consideration of $11.8 million, representing all of the warrants held by Bain Capital Life Sciences and its affiliates.

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. Bain Capital Life Sciences is the general partner of Bain Life Sciences Funds. The participation by Bain Life Sciences Funds was on the same terms as the other investors in the offering.

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. 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, 2021, we received net cash proceeds of $28.2 million resulting from sales of 2,878,567 shares of our common stock pursuant to the 2020 ATM Agreement. All of these shares were sold during the three months ended March 31, 2021. As of December 31, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

Preferred Stock Outstanding

In August 2021, all of the 4,140 shares of Series B Preferred Stock were converted into 4,140,000 shares of common stock. As of December 31, 2021, there were no shares of Series B Preferred Stock outstanding.

Warrants

During the year ended December 31, 2021, 3,958,650 of our common stock warrants were exercised. There was no exercise of our common stock warrants during the year ended December 31, 2020 and 2019. As of December 31, 2021, 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, 2021 (in thousands)
August 12, 2019	1,883	February 12, 2022	$ 4.50	1,883

As of February 28, 2022, all 1,882,600 of the outstanding warrants as of December 31, 2021 have been exercised or expired resulting in cash settlement of $8.5 million.

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.

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, 2021 and 2020, the estimated fair value of warrant liability was $18.0 million and $10.7 million, respectively. For the year ended December 31, 2021 and 2019, we recognized $49.4 million and $7.5 million increase in the estimated fair value of warrant liability, respectively, as a loss in other income (expense) in our consolidated statements of operations. 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.

15. Equity Plans and Stock-Based Compensation

Equity Plans

In January 2021, we adopted the Dynavax Technologies Corporation 2021 Inducement Award Plan ("2021 Inducement 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. In June 2021, we amended the 2021 Inducement Plan ("Amended 2021 Inducement Plan") to increase the number of shares of common stock reserved under the 2021 Inducement Plan to 3,250,000.

As of December 31, 2021, the 2018 Equity Incentive Plan, as amended, ("Amended 2018 EIP"), the Amended 2021 Inducement Plan and the Amended and Restated 2014 Employee Stock Purchase Plan are our active plans. 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.

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, 2021, there were 4,851,391 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, 2020	8,505	$ 11.57		
Options granted	3,894	10.49		
Options exercised	(1,035)	6.46		
Options cancelled:				
Options forfeited (unvested)	(521)	8.13		
Options expired (vested)	(444)	18.48		
Balance at December 31, 2021	10,399	$ 11.55	4.16	$ 42,756
Vested and expected to vest at December 31, 2021	10,029	$ 11.57	4.08	$ 41,321
Exercisable at December 31, 2021	5,796	$ 13.07	2.64	$ 20,488

The total intrinsic value of stock options exercised during the years ended December 31, 2021, 2020 and 2019 was $7.9 million, $0.1 million and $26,000, 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, 2021, 2020 and 2019 was $9.0 million, $13.8 million and $19.5 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, 2021, and activities during 2021 are summarized as follows:

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2020	1,794	$ 7.23
Granted	1,818	9.50
Vested	(537)	8.85
Forfeited	(424)	8.21
Non-vested as of December 31, 2021	2,651	$ 8.30

Stock-based compensation expense related to restricted stock units was approximately $7.9 million for the year ended December 31, 2021. The aggregate intrinsic value of the restricted stock units outstanding as of December 31, 2021, based on our stock price on that date, was $37.3 million.

The total fair value of restricted stock units vested during the years ended December 31, 2021, 2020 and 2019 was $4.7 million, $4.9 million and $7.9 million, respectively.

We granted performance-based restricted stock unit ("PSU") to certain executives in February 2021. These PSUs vest upon a specified market condition. The summary of PSU activities for the year ended December 31, 2021 is as follows:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2020	-	$ -
Granted	297	8.40
Forfeited	(60)	8.40
Non-vested as of December 31, 2021	237	$ 8.40

Stock-based compensation expense related to PSUs was approximately $1.8 million for the year ended December 31, 2021. The aggregate intrinsic value of the PSUs outstanding as of December 31, 2021, based on our stock price on that date, was $3.3 million. None of the PSUs vested as of December 31, 2021.

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 fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model. The fair value of each RSU is determined at the date of grant using our closing stock price. The fair value of each PSU is estimated using the Monte Carlo simulation method on the date of grant. The weighted-average assumptions used in the calculations of these fair value measurements are as follows:

	Stock Options			Market-Based Performance Stock Unit ("PSUs")	Employee Stock Purchase Plan		
	Year Ended December 31,			Year Ended December 31,	Year Ended December 31,		
	2021	2020	2019	2021	2021	2020	2019
Weighted-average fair value	$ 7.17	$ 3.91	$ 4.58	$ 8.40	$ 6.48	$ 2.82	$ 2.72
Risk-free interest rate	0.7%	1.0%	2.1%	From 0.03% to 1.92%	0.1%	0.9%	1.9%
Expected life (in years)	4.5	4.5	4.5	2.9	1.2	1.2	1.2
Expected Volatility	0.9	0.9	0.9	0.9	1.0	0.7	0.7

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. 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.

The Company has also granted performance-based equity awards to certain of our employees. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable. No stock-based compensation expense for awards with performance-based vesting criteria was recognized during the year ended December 31, 2021. We recognized stock-based compensation expense for awards with performance-based vesting criteria during the years ended December 31, 2020 and 2019 of $0.1 million and $0.5 million, respectively. As of December 31, 2021, approximately 117,000 shares underlying stock options and approximately 202,050 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, 2021.

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

	Year Ended December 31,		
	2021	2020	2019
Employees and directors stock-based compensation expense	$ 21,285	$ 13,484	$ 25,456

	Year Ended December 31,		
	2021	2020	2019
Research and development	$ 3,818	$ 1,000	$ 8,058
Selling, general and administrative	14,894	9,585	10,224
Cost of sales - product	553	619	1,088
Inventory	2,020	2,280	1,964
Restructuring	-	-	4,122
Total	$ 21,285	$ 13,484	$ 25,456

As of December 31, 2021, 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 $33.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 2 years. As of December 31, 2021, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $1.0 million. As of December 31, 2021, the total unrecognized compensation cost related to PSUs amounted to $0.2 million.

Employee Stock Purchase Plan

The Amended and Restated 2014 Employee Stock Purchase Plan (the “Employee Stock Purchase Plan”) provides for the purchase of common stock by eligible employees. In May 2021, our stockholders approved the amendment and restatement of the Employee Stock Purchase Plan to increase the authorized number of shares of common stock by 1,000,000. The maximum number of shares of common stock that may be issued under the Employee Stock Purchase Plan will not exceed 1,850,000 shares of common stock.

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, 2021, employees have acquired 217,270 shares of our common

stock under the Employee Stock Purchase Plan and 1,038,313 shares of our common stock remained available for future purchases under the Employee Stock Purchase Plan.

As of December 31, 2021, the total unrecognized compensation cost related to shares of our common stock under the Employee Stock Purchase Plan amounted to $1.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.5 years.

16. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. The Company's contribution to the 401(k) Plan was approximately $0.3 million, $0.2 million and $0.3 million for the years ended December 31, 2021, 2020 and 2019, 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

18. Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
U.S.	$ 75,954	$ (76,324)	$ (154,605)
Non U.S.	1,567	1,084	2,005
Total	$ 77,521	$ (75,240)	$ (152,600)

There was no income tax provision for the years ended December 31, 2020 and 2019. The components of the consolidated income tax provision for the year ended December 31, 2021 were as follows (in thousands):

	Year Ended December 31, 2021
Current	
Federal	$ 345
State	260
Non-US	203
Total current tax expense	808
Deferred	
Federal	-
State	-
Non-US	-
Total deferred tax expense	-
Total income tax expense	$ 808

No income tax expense was recorded for the years ended December 31, 2020 and 2019 due to a full valuation allowance. The difference between the consolidated income tax provision (benefit) and the amount computed by applying the federal statutory income tax rate to the consolidated income before income taxes was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Income tax provision (benefit) at federal statutory rate	$ 16,397	$ (15,756)	$ (32,046)
State tax	3,576	(3,194)	(3,153)
Business credits	(982)	(773)	(1,757)
Uncertain tax positions	424	193	5,426
Deferred compensation charges	131	809	4,600
Change in valuation allowance	(86,847)	19,009	22,715
Section 162(m) limitation	1,241	473	2,439
Mark-to-market of warrants	10,364	(866)	1,575
Net operating loss and tax credit limitation	56,459	-	-
Other	45	105	201
Total income tax expense	$ 808	$ -	$ -

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

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 155,503	$ 224,161
Research credit carryforwards	12,870	28,578
Lease liability	8,515	-
Stock compensation	5,798	-
Accruals and reserves	5,792	17,264
Other	212	3,250
Total deferred tax assets	188,690	273,253
Less valuation allowance	(179,253)	(266,100)
Net deferred tax assets	9,437	7,153
Deferred tax liabilities:		
Fixed assets	(3,283)	(275)
Operating lease right-of-use assets	(6,124)	(6,878)
Other	(30)	-
Total deferred tax liabilities	(9,437)	(7,153)
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. A high degree of judgment is required to determine if, and the extent to which, valuation allowances should be recorded against deferred tax assets. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Based on all available evidence, both positive and negative, and the weight of that evidence to the extent such evidence can be objectively verified, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more likely than not to be realized and, accordingly, has provided a valuation allowance. Given our current earnings, management believes that, within the next twelve months, sufficient positive evidence may become available to allow management to reach a conclusion that a portion of the valuation allowance recorded against the deferred tax assets held may be reversed. A reversal would result in an income tax benefit for the quarterly and annual fiscal period in which we release the valuation allowance. However, the exact timing and amount of a valuation allowance release are subject to change on the basis of the level of profitability that we actually achieve.

The valuation allowance decreased by $86.8 million during the year ended December 31, 2021 and increased by $19.0 million during the year ended December 31, 2020. The decrease in valuation allowance during the year ended December 31, 2021 was due to a decrease in our deferred tax assets, predominantly related to utilization of net operating losses and Section 382 limitations.

As of December 31, 2021, we had federal net operating loss carryforwards of approximately $303.8 million which begin to expire in the year 2022, federal net operating loss carryforwards of approximately $333.4 million, which do not expire and federal research and development tax credits of approximately $1.9 million, which expire in the years 2022 through 2041.

As of December 31, 2021, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $345.9 million, which expire in the years 2022 through 2041, and California state research and development tax credits of approximately $19.6 million, which do not expire.

As of December 31, 2021, we had net operating loss carryforwards for foreign income tax purposes of approximately $3.5 million, which do not expire.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits was $5.6 million and $10.6 million as of December 31, 2021 and 2020, 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, 2020	$ (10,565)
Tax positions related to the current year	
Additions	(308)
Reductions	-
Tax positions related to the prior year	
Additions	-
Reductions	5,258
Settlements	-
Lapses in statute	-
Balance at December 31, 2021	$ (5,615)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2021, there was no interest and $0.2 million of penalties recognized in the provision for income taxes. As of December 31, 2020, there was no interest or penalties related to unrecognized tax benefits 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, 2021, we experienced ownership changes in 2008, 2009, 2012, and 2019 which limit the future use of our pre-change federal and state net operating loss carryforwards and federal research and development tax credits. We excluded the net operating loss carryforwards and research and development tax credits that will expire as a result of the annual limitations in the deferred tax assets and corresponding uncertain tax positions as of December 31, 2021.

We are subject to income tax examinations for U.S. federal and state income taxes from 2002 forward. We are subject to tax examination in Germany from 2018 forward and in India from 2019 forward.

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, 2021. 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, 2021, 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, 2021, 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, 2021 and 2020, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021 and the related notes of the Company and our report dated February 28, 2022 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 28, 2022

(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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

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 2022 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, 2021.

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 “Compensation Discussion and Analysis,” “Summary Compensation Table,” “Grants of Plan Based Awards,” “Outstanding Equity Awards at Fiscal Year End,” and “Corporate Governance” 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 ACCOUNTANT 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 Income (Loss)

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

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

(b) Exhibits

		Incorporated by Reference				
Exhibit Number	Document	Exhibit Number	Filing	Filing Date	File No.	Filed Herewith
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.5	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.6	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	

3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	May 29, 2020	001-34207	
3.9	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	
4.1	Description of Capital Stock	4.1	10-K			X
4.2	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 and 3.9 above					
4.3	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.5	Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021	4.1	8-K	May 13, 2021	001-34207	
4.6	Form of Global Note, representing Dynavax Technologies Corporation's 2.5% Convertible Senior Notes due 2026	4.2	8-K	May 13, 2021	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+	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	
10.4†	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	

10.5†	Supply Agreement, dated November 2, 2016, between Company and Becton, Dickinson and Company	10.34	10-K	March 8, 2018	001-34207	
10.6†	Supply Agreement, dated October 1, 2012, between Company and Nitto Denko Avecia, Inc.	10.35	10-K	March 8, 2018	001-34207	
10.7†	Supply Agreement, dated July 27, 2016, between Company and West Pharmaceutical Services, Inc.	10.36	10-K	March 8, 2018	001-34207	
10.8+	Amended and Restated 2018 Equity Incentive Plan	10.1	10-Q	August 6, 2020	001-34207	
10.9+	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	
10.10+	Form of Option Grant Notice and Option Agreement under the 2018 Equity Incentive Plan	10.3	8-K	June 1, 2018	001-34207	
10.11+	Restricted Stock Unit Award Agreement for Directors under the 2018 Equity Incentive Plan					X
10.12	Office/Laboratory Lease, dated September 17, 2018, between the Company and Emery Station West, LLC	10.1	10-Q	November 6, 2018	001-34207	
10.13+	Chief Executive Officer Letter, dated December 13, 2019, between the Company and Ryan Spencer	10.17	10-K	March 11, 2020	001-34207	
10.14+	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	
10.15+	Form of Indemnification Agreement	10.1	10-Q	November 7, 2019	001-34207	
10.16	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	

10.17	Sublease, by and between Dynavax Technologies Corporation and Zymergen Inc., dated July 12, 2019	10.3	10-Q	November 7, 2019	001-34207	
10.18+	Dynavax Technologies Corporation U.S. Annual Bonus Plan	10.23	10-K	March 11, 2020	001-34207	
10.19	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	
10.20^	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	
10.21^	Letter Agreement, dated October 29, 2021, by and among the Company, Valneva Scotland Limited and Valneva Austria GmbH					X
10.22+	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	
10.23	Sales Agreement, dated August 6, 2020, between the Company and Cowen and Company, LLC	10.3	10-Q	August 6, 2020	001-34207	
10.24^	Agreement, dated January 29, 2021 between Company and Coalition for Epidemic Preparedness Innovations	10.31	10-K	February 25, 2021	001-34207	
10.25+	Offer Letter, dated December 14, 2020, by and between the Company and Kelly MacDonald	10.33	10-K	February 25, 2021	001-34207	
10.26^	First Amendment to Agreement, dated May 3, 2021, by and between the Company and Coalition for Epidemic Preparedness Innovations	10.1	10-Q	August 4, 2021	001-34207	
10.27+	Amended and Restated Dynavax Technologies Corporation 2021 Inducement Award Plan	10.3	10-Q	August 4, 2021	001-34207	

10.28+	Dynavax Technologies Corporation Amended and Restated 2014 Employee Stock Purchase Plan	Appendix A	DEF 14A	April 16, 2021	001-34207	
10.29	Form of Confirmation for Capped Call Transactions	10.1	8-K	May 13, 2021	001-34207	
10.30^	Supply Agreement, dated June 29, 2021, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc., and Clover Biopharmaceuticals (Hong Kong) Co., Limited	10.6	10-Q	August 4, 2021	001-34207	
10.31^	Supply Agreement, dated July 1, 2021, by and between Company and Biological E. Limited	10.7	10-Q	August 4, 2021	001-34207	
10.32	Commercial Lease Agreement, dated September 13, 2021, by and between Onyx Düsseldorf S.à r.l. and Dynavax GmbH	10.2	10-Q	November 4, 2021	001-34207	
10.33^	First Amendment to Commercial Manufacturing and Supply Agreement, dated September 10, 2021, by and between Baxter Pharmaceutical Solutions LLC and Dynavax Technologies Corporation	10.3	10-Q	November 4, 2021	001-34207	
10.34+	Non-Employee Director Compensation Policy					X
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Chief Executive Officer to Section 906 of the Sarbanes-Oxley Act of 2002					X

32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

EX—101.INS	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 28, 2022

By: /s/ KELLY MACDONALD

Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer)

Date: February 28, 2022

By: /s/ JUSTIN BURGESS

Justin Burgess
Controller
(Principal Accounting Officer)

Date: February 28, 2022

Signature	Title	Date
/s/ RYAN SPENCER **Ryan Spencer**	Chief Executive Officer *(Principal Executive Officer)*	February 28, 2022
/s/ KELLY MACDONALD **Kelly MacDonald**	Chief Financial Officer *(Principal Financial Officer)*	February 28, 2022
/s/ JUSTIN BURGESS **Justin Burgess**	Controller *(Principal Accounting Officer)*	February 28, 2022
/s/ SCOTT MYERS **Scott Myers**	Chairman of the Board	February 28, 2022
/s/ FRANCIS R. CANO **Francis R. Cano, Ph.D.**	Director	February 28, 2022
/s/ JULIE EASTLAND **Julie Eastland**	Director	February 28, 2022
/s/ ANDREW HACK **Andrew Hack, M.D., Ph.D.**	Director	February 28, 2022
/s/ DANIEL L. KISNER **Daniel L. Kisner, M.D.**	Director	February 28, 2022
/s/ BRENT MACGREGOR **Brent MacGregor**	Director	February 28, 2022
/s/ PETER R. PARADISO **Peter R. Paradiso**	Director	February 28, 2022
/s/ PEGGY V. PHILLIPS **Peggy V. Phillips**	Director	February 28, 2022
/s/ NATALE S. RICCIARDI **Natale S. Ricciardi**	Director	February 28, 2022
/s/ ELAINE D. SUN **Elaine D. Sun**	Director	February 28, 2022

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. 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.

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.

Choice of Forum

Our bylaws provide that, unless we consent to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court’s having personal jurisdiction over the indispensable parties named as defendants. Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

DYNAVAX TECHNOLOGIES CORPORATION
2018 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the accompanying Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), Dynavax Technologies Corporation (the "***Company***") has granted you a Restricted Stock Unit Award (the "***Award***") under the Dynavax Technologies Corporation 2018 Equity Incentive Plan (the "***Plan***") for the number of restricted stock units (the "***Restricted Stock Units***") set forth in the Grant Notice. This Award is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Capitalized terms not explicitly defined in this Agreement but defined in the Plan or the Grant Notice will have the same definitions as in the Plan or the Grant Notice.

1. GRANT OF THE AWARD. This Award represents your right to be issued on a future date (as set forth in Section 6) one share of Common Stock for each Restricted Stock Unit subject to this Award that vests in accordance with the Grant Notice and this Agreement. This Award was granted in consideration of your services to the Company or an Affiliate. Except as otherwise provided herein, you will not be required to make any payment to the Company (other than services to the Company or an Affiliate) with respect to your receipt of the Award, the vesting of the Restricted Stock Units or the issuance of any shares of Common Stock in respect of this Award.

2. VESTING. Subject to the limitations contained herein, this Award will vest, if at all, in accordance with the vesting schedule set forth in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, you will forfeit (at no cost to the Company) any Restricted Stock Units subject to this Award that have not vested as of the date of such termination and you will have no further right, title or interest in such Restricted Stock Units.

3. NUMBER OF RESTRICTED STOCK UNITS AND SHARES OF COMMON STOCK.

(a) The number of Restricted Stock Units subject to this Award, as set forth in the Grant Notice, will be adjusted for Capitalization Adjustments, if any, as provided in the Plan.

(b) Any additional Restricted Stock Units and any shares of Common Stock, cash or other property that become subject to this Award pursuant to this Section 3 will be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of issuance as applicable to the other Restricted Stock Units subject to this Award to which they relate.

(c) No fractional shares or rights for fractional shares of Common Stock will be created pursuant to this Section 3. Any fractional shares that may be created by the adjustments referred to in this Section 3 will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You will not be issued any shares of Common Stock in respect of this Award unless either (i) such shares are registered under the Securities Act or (ii)

the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. This Award also must comply with all other applicable laws and regulations governing this Award, and you will not receive any shares of Common Stock in respect of this Award if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. Transferability. This Award is not transferable, except by will or by the laws of descent and distribution and prior to the time that shares of Common Stock in respect of this Award have been issued to you, you may not transfer, pledge, sell or otherwise dispose of any portion of the Restricted Stock Units or the shares of Common Stock in respect of this Award. For example, you may not use any shares of Common Stock that may be issued in respect of this Award as security for a loan, nor may you transfer, pledge, sell or otherwise dispose of such shares. This restriction on transfer will lapse upon issuance to you of the shares of Common Stock in respect of this Award.

6. Issuance of Shares.

(a) The issuance of any shares of Common Stock in respect of this Award is subject to satisfaction of the tax withholding obligations set forth in Section 10. The form of such issuance (*e.g.*, a stock certificate or electronic entry evidencing such shares) will be determined by the Company.

(b) In the event one or more Restricted Stock Units subject to this Award vests, the Company will issue to you, on the Settlement Date (as defined below), one (1) share of Common Stock for each Restricted Stock Unit that vests on or prior to the Settlement Date; *provided*, *however*, that if the Settlement Date falls on a date that is not a business day, such shares will instead be issued to you on the next following business day.

For purposes of this Agreement, the "***Settlement Date***" will mean the earlier of (i) the date that is six (6) months and one (1) day following the date on which you experience a "separation from service" (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) as a Director and (ii) a Change in Control that constitutes a "change in control event" (as determined under Treasury Regulations Section 1.409A-3(i)(5)).

7. Dividends. You will receive no benefit or adjustment to this Award with respect to any cash dividend, stock dividend or other distribution except as provided in the Plan with respect to a Capitalization Adjustment.

8. Restrictive Legends. The shares of Common Stock issued in respect of this Award will be endorsed with appropriate legends, if any, as determined by the Company.

9. Award Not a Service Contract. This Award is not an employment or service contract, and nothing in this Award will be deemed to create in any way whatsoever any obligation on your part to continue in the service of the Company or any Affiliate, or on the part of the Company or any Affiliate to continue such service. In addition, nothing in this Award will obligate the Company or an Affiliate, their respective stockholders, boards of directors, Officers or

Employees to continue any relationship that you might have as an Employee, Director or consultant for the Company or an Affiliate.

10. TAX WITHHOLDING OBLIGATIONS.

(a) On or before the time you receive a distribution of any shares of Common Stock in respect of this Award, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you agree to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with this Award (the "***Withholding Taxes***"). Specifically, the Company or an Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes relating to this Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or an Affiliate; (ii) causing you to tender a cash payment; (iii) permitting you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares of Common Stock to be issued in connection with this Award to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with this Award with a Fair Market Value (measured as of the date the shares of Common Stock are issued to you) not in excess of the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of this Award as a liability for financial accounting purposes).

(b) Unless the Withholding Taxes of the Company and/or any Affiliate are satisfied, the Company will have no obligation to issue to you any Common Stock.

(c) In the event the Company's obligation to withhold arises prior to the issuance to you of Common Stock or it is determined after the issuance of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

11. UNSECURED OBLIGATION. This Award is unfunded, and as a holder of vested Restricted Stock Units, you will be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares of Common Stock or other property pursuant to this Agreement.

12. STOCKHOLDER RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares of Common Stock to be issued pursuant to this Award until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

13. Other Documents. You hereby acknowledge receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares of Common Stock only during certain "window" periods in effect from time to time and the Company's insider trading policy.

14. Notices. Any notices provided for in this Agreement or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to this Award or participation in the Plan by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. Governing Plan Document. This Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of this Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as otherwise expressly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the terms of the Plan, the terms of the Plan will control.

16. Severability. If any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

17. Effect on Other Employee Benefit Plans. The value of this Award will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

18. Choice of Law. The interpretation, performance and enforcement of this Agreement will be governed by the law of the state of Delaware without regard to such state's conflicts of laws rules.

19. Amendment. Any amendment to this Agreement must be in writing, signed by a duly authorized representative of the Company. Notwithstanding anything in the Plan to the contrary, the Board reserves the right to amend this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, interpretation, ruling, or judicial decision.

20. Compliance with Section 409A of the Code. This Award is intended to comply with, and will be construed to the greatest extent possible as consistent with, the requirements of Section 409A of the Code. If (i) you are deemed by the Company at the time of your "separation from service" (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code and (ii) any of the payments upon such separation from service set forth herein are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to you prior to the earliest of (a) the date that is six (6) months and one (1) day after the date of such separation from service, (b) the date of your death, or (c) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 20 will be paid in a lump sum to you, and any remaining payments due will be paid as otherwise provided herein. Each installment of Restricted Stock Units that vests under this Award is a "separate payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2).

21. Tax Consequences. The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by accepting this Award, you have agreed that you have done so or knowingly and voluntarily declined to do so.

22. Miscellaneous.

(a) The rights and obligations of the Company under this Award will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of this Award.

(c) You acknowledge and agree that you have reviewed this Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting this Award, and fully understand all provisions of this Award.

(d) This Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Restricted Stock Unit Award Agreement will be deemed to be accepted by you upon your acceptance of the Restricted Stock Unit Award Grant Notice to which it is attached.

Exhibit 10.21

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.

From: **Valneva Scotland Limited** ("**Purchaser**")
Oakbank Park Road,
Livingston, Scotland
EH53 0TG, United Kingdom

And: **Valneva Austria GmbH** (**"Valneva Austria**")
Campus Vienna Biocenter 3
1030 Vienna
Austria

To: **Dynavax Technologies Corporation** ("**Dynavax**")
2100 Powell Street, Suite 900
Emeryville, CA 94308
USA

28 October 2021 (the "**Amendment Date**")

Dear Sirs

SUPPLY AGREEMENT BETWEEN DYNAVAX, PURCHASER AND VALNEVA AUSTRIA DATED 12 SEPTEMBER 2020 (THE "AGREEMENT")

To the extent not otherwise defined in this letter (including Appendix One hereto, which is incorporated herein by this reference) ("**Amendment**"), capitalized terms used but not otherwise defined in this Amendment will have the same meanings as given to them in the Agreement.

The Parties agree that, with effect from the Amendment Date (subject to execution and delivery of this Amendment by all Parties as provided below), the Agreement shall be amended as set forth in this Amendment.

The Agreement, as varied by this Amendment, shall remain in full force and effect in accordance with its terms.

This Amendment may be executed in two or more counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument, but will not be effective until each Party has executed and delivered at least one counterpart to the other Parties. This Amendment may be executed and delivered electronically, including by DocuSign, or by facsimile, and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered.

This Amendment, and all questions regarding the existence, validity, interpretation, breach, or performance of this Amendment, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of laws principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded. Section 11.3 of the Agreement shall apply to this Amendment, *mutatis mutandis*.

[*Signature page follows*]

Please confirm your acceptance of the terms of this Amendment by signing and returning to us a copy of this Amendment.

Yours faithfully

Valneva Scotland Limited

Signed: /s/ Thomas Lingelbach /s/ Franck Grimaud

Name: Thomas Lingelbach Franck Grimaud
Director Director

Date: 29 October 2021

Valneva Austria GmbH

Signed: /s/ Dr. Juan Carlos Jaramillo /s/ Frederic Jacotot

Name: Dr. Juan Carlos Jaramillo Frederic Jacotot
Managing Director Managing Director

Date: 29 October 2021

We agree to the above proposal.

For and on behalf of **Dynavax Technologies Corporation**

Signed: /s/ David Novack

Name: David Novack

Date: 10/28/2021

Attachment: Appendix One

APPENDIX ONE

1. The Parties agree and confirm that, in accordance with Section 2.5 of the Agreement, each of the Purchase Orders identified below, which collectively constitute all Purchase Orders which have been placed by Purchaser prior to the Amendment Date in respect of CpG Adjuvant which has not, as at the Amendment Date, been delivered to Purchaser, are hereby cancelled:

Purchase Order No.	**Date**
PO21-000925	March 25, 2021
PO21-000927	March 25, 2021

The Parties hereby confirm that Dynavax is entitled to retain all Advance Payments paid by Purchaser to Dynavax under the Agreement prior to the Amendment Date, and Purchaser shall not be entitled to any refund thereof.

2. The Parties wish to further vary the Agreement and agree that, with effect from the Amendment Date:

(a) Sections 2.2 is deleted in its entirety and replaced as follows:

"**2.2 Commitments and Orders.**

(a) Binding Purchase Order. On the Amendment Date, Purchaser has submitted a binding Purchase Order for [***] of CpG Material, which has been accepted by Dynavax, as set out in the table below:

KG of CpG Material	**Order Deadline**	**Delivery Date**	**Final Payment paid on Delivery Date**
[***]	[***]	[***]	[***], being [***] of the aggregate Cost per Dose of such CpG Material and constituting the Final Payment for such CpG Material. Dynavax acknowledges and agrees that it shall be deemed to have received the Advance Payment for such CpG Material of [***], being [***] of the aggregate Cost per Dose of such CpG Material.

(b) Optional Purchase Order. As soon as reasonably practicable, Dynavax shall deliver written notice to Purchaser as to whether or not Dynavax can reasonably extend the shelf life of such CpG Material to [***]. If Dynavax determines not to extend such shelf life, Purchaser shall have the right to submit to Dynavax, within five (5) Business Days from delivery by Dynavax of such written notice, one (1) (and only one) additional Purchase Order under this Agreement for a maximum of [***] of CpG Material as set forth in the table below, which Dynavax will be obliged to accept:

KG of CpG Material	Delivery Date	Final Payment paid on Delivery Date
[***]	[***]	[***], being [***] of the aggregate Cost per Dose of such CpG Material and constituting the Final Payment for such CpG Material. Dynavax acknowledges and agrees that it shall be deemed to have received the Advance Payment for such CpG Material of [***], being [***] of the aggregate Cost per Dose of such CpG Material.

(c) No Additional Quantities. For clarity, the sum of the number of kilograms of CpG Material set forth in the table in Section 2.2(a), and, if applicable, the number of kilograms of CpG Material set forth in the table in Section 2.2(b) (collectively, the "**Commitment**"), represents the maximum amount of CpG Material that Purchaser has the right to order and purchase, and Dynavax is obligated to sell and supply to Purchaser, under this Agreement from and after the Amendment Date. From the Amendment Date, Purchaser shall have no right to submit, and Dynavax shall have no obligation to accept, any Purchase Order from Purchaser for CpG Material under this Agreement, other than the Purchase Orders specified in Sections 2.2(a) and 2.2(b). Should Purchaser wish to purchase from Dynavax, and Dynavax be willing to sell and supply to Purchaser, any quantity of CpG Adjuvant in excess of the Commitment, the terms and conditions of any such purchase, sale and supply, including the price of any such CpG Adjuvant, would be subject to negotiation and mutual written agreement of the Parties."

(b) Section 2.3 of the Agreement is deleted in its entirety.

(c) The first sentence of Section 2.4(a) of the Agreement is deleted in its entirety.

(d) Notwithstanding the provisions of Section 2.4(b) of the Agreement, except for the obligation set forth in Section 2.2(b) of this Amendment to deliver written notice to Purchaser regarding whether Dynavax can reasonably extend the shelf life of the CpG Material already received by Purchaser under the Agreement (as amended by this Amendment), Dynavax shall have no additional obligation to extend the shelf life of CpG Material (including CpG Material previously delivered).

(e) Section 2.5(b) of the Agreement is deleted in its entirety and replaced as follows:

"**(b)** The Parties agree that Purchaser, in its sole discretion, may cancel the Purchase Order placed under Section 2.2(a) of this Agreement by written notice to Dynavax on or before the Order Deadline (1 December 2021). If such Purchase Order is cancelled on or before the Order Deadline, Dynavax will not be required to deliver the CpG Material which is the subject of that Purchase Order, Purchaser shall not be required to pay the Final Payment for such CpG Material, and, for clarity, Purchaser shall not be entitled to any refund of the Advance Payment received by Dynavax in connection with such Purchase Order."

(f) Notwithstanding the first two sentences of Section 3.1 of the Agreement, the purchase price (and aggregate Cost per Dose) of all CpG Material supplied by Dynavax to Purchaser after the Amendment Date under Section 2.2 of the Agreement (as amended by this Amendment) is as specified in such Section 2.2.

(g) Section 3.2 of the Agreement is deleted in its entirety and replaced as follows:

"**3.2 Invoice and Payment.** In respect of the CpG Material ordered in any Purchase Order submitted by Purchaser pursuant to Section 2.2(a) or 2.2(b) of this Agreement, Purchaser is

deemed to have paid, and Dynavax is deemed to have received, prior to the Amendment Date, [***] of the aggregate Cost per Dose of such CpG Material as shown in the tables in such Section (the "**Advance Payment**"), and Dynavax will invoice Purchaser for [***] of the aggregate Cost per Dose of such CpG Material, as shown in the tables in such Section (the "**Final Payment**"), upon delivery of such CpG Material in accordance with Section 2.4(a). Purchaser shall pay each invoice, in U.S. Dollars, within [***] days after receipt of such invoice by wire transfer of immediately available funds into an account designated by Dynavax. If Purchaser disputes any invoiced amount hereunder (or a portion thereof), Purchaser shall timely pay any undisputed portion of the invoiced amount in accordance with the preceding sentence and shall notify Dynavax in writing of the disputed amount, including the basis on which Purchaser disputes such amount, within [***] days after receipt of the invoice.*"*

(h) Section 10.1 of the Agreement is deleted in its entirety and replaced as follows:

"**10.1 Term.** This Agreement commenced on 13 September 2020 (the "**Effective Date**") and, unless earlier terminated by the Parties pursuant to Section 10.2, will continue until the delivery by Dynavax to Purchaser in accordance with this Agreement of the quantity of CpG Material specified in Section 2.2(a), unless Purchaser timely submits a Purchase Order for the additional quantity of CpG Material specified in Section 2.2(b), in which case it will continue until the delivery by Dynavax to Purchaser in accordance with this Agreement of the quantity of CpG Material specified in Section 2.2(b)."

(i) The final sentence of Section 10.5 of the Agreement is deleted in its entirety and replaced as follows:

"Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Article 1 (Definitions), Section 2.7 (Inspection and Acceptance), Article 5 (Use of CpG Material), Article 6 (Intellectual Property), Article 7 (Confidentiality), Article 9 (Indemnification), Section 10.5 (Effects of Termination; Survival), and Article 11 (General Provisions)."

[End of Appendix One]

Exhibit 10.34

DYNAVAX TECHNOLOGIES CORPORATION
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
EFFECTIVE OCTOBER 2021

Directors who are not Employees ("Non-Employee Directors") shall receive equity and cash compensation as set forth below. Capitalized terms used in this Policy, unless otherwise defined herein, have the meaning given to them in the Company's Amended and Restated 2018 Equity Incentive Plan (the "2018 Plan") or any successor equity incentive plan, if applicable.

EQUITY COMPENSATION

Initial Grant; Subsequent Grant

Each Non-Employee Director shall be granted, automatically and without further action by the Board or the Compensation Committee of the Board, a Nonstatutory Stock Option ("NSO") and a Restricted Stock Unit Award ("RSU"), together equal to the stock option equivalent of 60,000 shares of Common Stock (collectively, an "Initial Grant") on the date on which such Non-Employee Director is first appointed or elected to the Board, using the methodology and subject to the terms and limitations and described below.

In addition, on the date of and immediately following each annual meeting of the Company's stockholders, each Non-Employee Director who continues as a Non-Employee Director following such annual meeting shall be granted, automatically and without further action by the Board or the Compensation Committee of the Board, an NSO and an RSU, together equal to the stock option equivalent of 30,000 shares of Common Stock (collectively, a "Subsequent Grant"), using the methodology and subject to the terms and limitations and described below. Each Non-Employee Director's first Subsequent Grant shall be pro-rated as follows based on the number of months that have elapsed since the date on which such Non-Employee Director was first appointed or elected to the Board:

Service Period from Initial Date of Appointment or Election	Pro-Rated Subsequent Grant
10 months or more	100% of grant (option equivalent of 30,000 shares)
7 months or more, but less than 10	75% of grant (option equivalent of 22,500 shares)
4 months or more, but less than 7	50% of grant (option equivalent of 15,000 shares)
1 month or more, but less than 4	25% of grant (option equivalent of 7,500 shares)
Less than 1 month	No grant

Each Initial Grant and each Subsequent Grant will be delivered such that approximately 75% of the value is delivered as an NSO and approximately 25% of the value is delivered as an RSU, using the methodology for determining actual share amounts and the stock option to restricted stock unit award ratio most recently approved by the Board or the Compensation Committee of the Board and subject to any limits on compensation payable to Non-Employee Directors contained in the 2018 Plan or any successor plan, as applicable. To the extent necessary to reduce the size of an Initial Grant or a Subsequent Grant to comply with any limit set forth in the 2018 Plan or any successor plan, as applicable, the number of option equivalent shares shall be reduced automatically and without further action by the Board or the Compensation Committee of the Board to the amount necessary to comply with such limit and then the methodology described in the first sentence of this paragraph shall be applied.

The Initial Grants and the Subsequent Grants shall be granted under and subject to the terms and conditions of the 2018 Plan, or any successor plan (including, but not limited to, any limits on compensation payable to non-employee directors contained in the 2018 Plan or any successor plan), and the terms of the award agreements entered into with each Non-Employee Director in connection with such awards. In the event of any inconsistency between the 2018 Plan, or any successor plan, and this Non-Employee Director Compensation Plan, this Non-Employee Director Compensation Policy shall control.

NSO Vesting; RSU Vesting and Settlement

Each Initial Grant shall vest as follows: 1/3rd of the shares vest on each of the one, two and three year anniversaries of the date of grant, such that the NSO will be fully vested and exercisable and the RSU will be fully vested three years after the date of grant, subject to the Non-Employee Director's Continuous Service through the applicable vesting date.

Each Subsequent Grant shall vest as follows: 100% of the shares vest on the one-year anniversary of the date of grant, such that the NSO will be fully vested and exercisable and the RSU will be fully vested one year after the date of grant, subject to the Non-Employee Director's Continuous Service through the applicable vesting date.

Each RSU shall be settled at the time set forth in the applicable award agreement. Receipt of the shares of Common Stock issuable upon vesting of RSUs shall be deferred until the earlier of (i) the date that is six months and one day after "separation from service" (as defined in Treasury Regulations Section 1.409A-1(h), without regard to alternate definitions thereunder) as a director and (ii) a Change in Control (as defined in the 2018 Plan or any successor plan) that also constitutes a "change in control event" (as determined under Treasury Regulations Section 1.409A-3(i)(5)); provided, that such deferral is (a) in compliance with Section 409A of the Internal Revenue Code of 1986, as amended, and the Department of Treasury final regulations and guidance thereunder, and (b) pursuant to such terms and conditions as the Board or the Compensation Committee of the Board may determine in its discretion.

NSO Exercise Price; RSU Consideration

The exercise price per share of Common Stock of each NSO shall be 100% of the Fair Market Value per share on the date of grant. With respect to RSUs, no payment to the Company will be required in connection with vesting or the issuance of shares of Common Stock.

CASH COMPENSATION

Annual Fees

Each Non-Employee Director shall receive an annual retainer fee of $50,000, except that the Chairman of the Board shall receive an annual retainer fee of $100,000. Such annual retainer fees will be paid in quarterly installments, in advance, at the beginning of each fiscal quarter.

Committee Fees

The Chairman of the Audit Committee shall receive an annual retainer of $20,000, and each additional member of the Audit Committee shall receive an annual retainer of $10,000.

The Chairman of the Compensation Committee shall receive an annual retainer of $15,000, and each additional member of the Compensation Committee shall receive an annual retainer of $7,000.

The Chairman of the Nominating and Governance Committee shall receive an annual retainer of $10,000, and each additional member of the Nominating and Governance Committee shall receive an annual retainer of $5,000.

Such annual retainer fees will be paid in quarterly installments, in advance, at the beginning of each fiscal quarter.

Pro-Rated Fees and Limit on Fees

If a Non-Employee Director joins the Board or a committee of the Board effective as of a date other than the first day of a fiscal quarter, the first quarterly installment for each applicable annual retainer fee set forth above will be pro-rated, based on the number of days served in the fiscal quarter of appointment, with regular full quarterly installments made thereafter. All annual cash retainers fees are vested upon payment.

All annual cash retainer fees are subject to any limits on compensation payable to non-employee directors contained in the 2018 Plan or any successor plan. To the extent necessary to reduce the cash retainer fees to comply with any limit set forth in the 2018 Plan or any successor plan, as applicable, such fees shall be reduced automatically and without further action by the Board or the Compensation Committee of the Board to the amount necessary to comply with such limit.

Travel and Related Costs

Reasonable travel and related costs associated with attending Board and committee meetings, and/or incurred in connection with the performance of Board business, shall be reimbursed. The Board member is required to submit proper documentation for reimbursement.

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, 333-241674, 333-258469 and 333-253515) 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, the Amended and Restated 2018 Equity Incentive Plan and the 2021 Inducement Award Plan of Dynavax Technologies Corporation;

of our reports dated February 28, 2022, 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, 2021.

/s/ Ernst & Young LLP

San Francisco, California

February 28, 2022

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 28, 2022

Exhibit 31.2

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

CERTIFICATIONS

I, Kelly MacDonald, 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/ KELLY MACDONALD

Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer)

Date: February 28, 2022

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, 2021, 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 28th day of February, 2022.

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, Kelly MacDonald, 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, 2021, 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 her hand hereto as of the 28th day of February, 2022.

By: /s/ KELLY MACDONALD

Kelly MacDonald
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.