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, 2024

☐ **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 720
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	Nasdaq Global Select Market
Preferred Share Purchase Rights	N/A	Nasdaq Global Select Market

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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, 2024 as reported on the Nasdaq Global Select Market, was approximately $0.8 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 18, 2025, the registrant had outstanding 124,070,829 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2025 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, 2024.

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

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DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, 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 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, manufacture and commercialization of other vaccines containing our CpG 1018 adjuvant, including any current or potential vaccine or vaccine candidate that stems from any of our collaborations, our ability to manufacture sufficient supply of CpG 1018 adjuvant to meet potential future demand in connection with new vaccines, our ability to advance our pipeline programs, including our shingles and plague programs, and to otherwise develop and expand our clinical research pipeline, meet regulatory requirements, including post-marketing obligations and commitments, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, liquidity and cash needs (including our ability to collect on accounts receivables), anticipated future revenue, 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 comparable terminology. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this 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 after the date they are made.

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 carefully consider the risks and uncertainties described herein as part of your evaluation of an investment in our securities:

- HEPLISAV-B has been approved in the United States ("U.S."), the European Union ("EU") and the United Kingdom and launched in the U.S. and Germany, 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 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 have incurred annual net losses in most years since our inception and could continue to incur significant losses if we do not successfully commercialize HEPLISAV-B, launch new products and/or significant sales of our CpG 1018 adjuvant do not resume. 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.
- 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 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.
- 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 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 in part reliant upon third parties to manufacture on our behalf.
- 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 U.S. Food and Drug Administration (“FDA”), EU and comparable foreign 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 authorities 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 future revenues, if any.
- HEPLISAV-B and all of our clinical programs rely on oligonucleotide toll-like receptor (“TLR”) agonists. In the event of serious adverse events relating to TLR agonists, we may be required to reduce the scope of, or discontinue, our operations, or reevaluate the viability of strategic alternatives.

- 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.
- 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.
- 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.
- 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.
- As we plan for the broader commercialization of our HEPLISAV-B vaccine and for the requisite capacity to manufacture our CpG 1018 adjuvant, our financial commitments for manufacturing and supply capacity might outpace actual demand for our products.
- We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates outside of the U.S., the European Union and the United Kingdom, requiring a significant additional 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 rely on clinical research organizations ("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 a biopharmaceutical company, we engage CROs to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with good clinical practices ("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.
- If third parties assert that we have infringed their patents or other proprietary rights or challenge our patents or other proprietary rights, we may become involved in disputes and litigation that would be costly, time consuming and have a negative impact on the commercialization of our current products and delay or prevent development or commercialization of our product candidates.
- Our stock price is subject to volatility, and your investment may suffer a decline in value.
- 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.
- Servicing our Convertible Notes (defined below) requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Conversion of the Convertible Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.
- 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 our information technology systems or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

PART I

ITEM 1. BUSINESS

OUR COMPANY

We are a commercial stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. We are currently focused on our efforts to drive long-term shareholder value by maximizing utilization of our HEPLISAV-B® hepatitis B vaccine, expanding our own portfolio of innovative vaccine candidates leveraging our proven CpG 1018® adjuvant technology, and identifying strategic opportunities to accelerate growth through both commercial and research collaborations.

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

Our first marketed product, HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the United States ("U.S."), the European Union ("EU") and the United Kingdom for prevention of infection caused by all known subtypes of hepatitis B virus ("HBV") in adults aged 18 years and older. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S., EU and the United Kingdom. In Phase 3 trials, HEPLISAV-B demonstrated faster and higher rates of protection with two doses in one month compared to other currently approved hepatitis B vaccines, which require three doses over six months, with similar safety profiles. 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 aged 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 in May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. In March 2023, we received marketing authorization in the United Kingdom for HEPLISAV-B for the active immunization against hepatitis B virus infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

Pipeline Programs

We are advancing a pipeline of differentiated product candidates that leverage our CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs. These programs include vaccine candidates under development for shingles and plague and additional vaccine programs in preclinical development.

- Shingles vaccine program: Z-1018 is an investigational vaccine candidate being developed for the prevention of shingles in adults aged 50 and older.
- Plague vaccine program: We are developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018 in collaboration with and fully funded by the U.S. Department of Defense ("DoD").

Additionally, we manufacture and have supplied in the past CpG 1018 adjuvant, the adjuvant used in HEPLISAV-B, through both commercial supply agreements and preclinical and clinical research collaborations with third-party organizations.

Adjuvant Technology Overview: Toll-like Receptor Targeted 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 the first line of defense against viruses, bacteria and other potential pathogens. Importantly, the innate response initiates and regulates the generation of an adaptive immune response composed of highly specific antibodies and T cells. Compounds used in vaccine products 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 recognize bacterial and viral nucleic acids. This work resulted in the identification of proprietary unmethylated 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 establishing long-term immunity. TLR9 stimulation particularly helps generate Th1 immune responses that are important to control pathogens such as viruses and bacteria. 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 as shown in multiple clinical trials in our HEPLISAV-B and COVID-19 vaccine collaboration programs.

Key 2024 Business and Financial Highlights

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

HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S. and EU that enables series completion with only two doses in one month. Hepatitis B vaccination is universally recommended for adults aged 19-59 in the U.S.

- We recognized $268.4 million of HEPLISAV-B product revenue during the year ended December 31, 2024, representing a 26% increase compared to the year ended December 31, 2023. This increase was primarily driven by an increase in the adult hepatitis B vaccine market and HEPLISAV-B market share gains in the U.S. in 2024, compared to 2023.
- HEPLISAV-B estimated total market share in the U.S. increased to approximately 44% at the end of 2024, compared to approximately 42% at the end of 2023.
- We continue to expect the hepatitis B adult vaccine market in the U.S. to expand to a peak of over $900.0 million in annual sales by 2030, with HEPLISAV-B expected to achieve at least 60% total market share. Additionally, we believe the HEPLISAV-B U.S. market opportunity will remain substantial beyond 2030 due to the ongoing penetration of the unvaccinated eligible adult population, observed revaccination practices by healthcare providers, and continued gains in market share.
- We generated $66.5 million in cash from operating activities during the year ended December 31, 2024 and ended the year with $713.8 million in cash and cash equivalents and marketable securities.
- We reported a net income of $27.3 million during the year ended December 31, 2024.

Advance Clinical Pipeline Leveraging our Proven Adjuvant Technology

We are advancing a pipeline of product candidates that leverage our CpG 1018 adjuvant, which has demonstrated its ability to enhance the immune response with a favorable tolerability profile in a wide range of clinical trials and real-world commercial use.

Shingles vaccine program:

Z-1018 is an investigational vaccine candidate being developed for the prevention of shingles in adults aged 50 years and older.

- We are currently conducting a randomized, active-controlled, dose escalation, multicenter Phase 1/2 trial to evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix® in 441 healthy adults aged 50 to 69.
- In the fourth quarter of 2024, we completed enrollment in the trial, and we anticipate reporting top line immunogenicity and safety data in the third quarter of 2025.

Plague vaccine candidate:

We are developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018® in collaboration with, and fully funded by, the U.S. Department of Defense ("DoD").

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the two-dose plague vaccine adjuvanted with CpG 1018, we and the DoD executed a new agreement for approximately $30.0 million through the first half of 2027 to support additional clinical and manufacturing activities, including a Phase 2 clinical trial expected to initiate in the third quarter of 2025.

HEPLISAV-B for Adults on Hemodialysis:

We are developing a four-dose HEPLISAV-B vaccine regimen for adults on hemodialysis.

- In the fourth quarter of 2024, we received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support our sBLA filing for adults on hemodialysis.

Tdap vaccine program:

- In November 2024, we announced that we have decided to discontinue development of our Tdap-1018 program based on results from a long-term Phase 1 extension study that did not demonstrate a differentiated profile that we believe would be successful commercially.

OUR STRATEGY

Our vision is to continue building a leading vaccines company dedicated to developing and commercializing innovative vaccines to help protect the world against infectious diseases. Our strategy is focused on our core priorities: drive growth in our HEPLISAV-B commercial vaccine, advance a differentiated vaccine pipeline, and identify strategic opportunities to accelerate growth. Key elements of our strategy include:

- Increase our HEPLISAV-B vaccine market share to become the market leader in the future;
- Maximize total addressable HEPLISAV-B vaccine market based on the CDC's Advisory Committee on Immunization Practices ("ACIP") Universal Recommendation;
- Leverage HEPLISAV-B vaccine as a foundational commercial asset to support company growth and pipeline development;
- Deliver on our innovative and diversified pipeline leveraging CpG 1018 adjuvant with proven antigens;
- Build an adult vaccine portfolio of best-in-class products;
- Advance innovative pre-clinical and discovery efforts leveraging collaborations;
- Continue disciplined allocation of capital aligned with corporate strategy to deliver long-term value through internal and external innovation; and
- Pursue external opportunities with high synergy assets in vaccines, or other modalities in infectious diseases, to further leverage our expertise and capabilities.

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

Our first commercial product, HEPLISAV-B [Hepatitis B Vaccine, (Recombinant), Adjuvanted], is approved by the FDA, the European Commission and the UK Medicines and Healthcare products Regulatory Agency for prevention of infection caused by all known subtypes of HBV in adults aged 18 years and older. HEPLISAV-B combines CpG 1018 adjuvant, 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 HBV. It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. 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 254.0 million people were living with chronic hepatitis B in 2022, and that in the same year hepatitis B resulted in an estimated 1.1 million deaths primarily from liver cancer. In addition, the CDC estimated that in 2021 approximately 580,000 to 1.2 million people in the U.S. were living with HBV infection. There was a total of 2,045 new cases of acute hepatitis B reported to the CDC in 2021. However, after adjusting for under-ascertainment and under-reporting, the CDC estimated that 14,229 acute hepatitis B cases occurred in the U.S. in 2021.

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, and such recommendation was published in April 2022. 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 U.S. who should be vaccinated against hepatitis B under the CDC recommendation. Based on this opportunity, we launched a series of 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. Such efforts have driven an increase in HEPLISAV-B demand and market share in the U.S. in 2024 compared to 2023.

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%).

We have 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., the EU and the United Kingdom 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 103 people are targeting customers that we believe have the highest impact on adult hepatitis B vaccine utilization in the U.S. We deploy our sales force to the physician or pharmacist level, as well as at the procurement level within respective healthcare segments where vaccines are utilized. Our primary objectives are to both increase market share and increase market size over time.

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. If we do receive approval of this dosing schedule, we expect to add dialysis centers to our personal promotion efforts. We submitted an sBLA for HEPLISAV-B vaccination of adults on hemodialysis to the FDA and received a Complete Response Letter ("CRL") in May 2024 that stated the data were insufficient to support the immunogenicity and safety of the four-dose regimen.We are exploring approaches to address the deficiencies identified in the CRL. In the fourth quarter of 2024, we received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support our sBLA filing for adults on hemodialysis. We expect to resubmit our sBLA for HEPLISAV-B vaccination of adults on hemodialysis to the FDA in 2025.

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 is believed to drive 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 safety 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 influenza, other infectious diseases, and particularly COVID-19 across a variety of vaccine platforms.

Our Vaccine Research and Development Pipeline

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

Shingles Vaccine Program

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 global shingles vaccine market was over $4.0 billion in 2024. 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 adjuvant has shown the ability to generate high levels of CD4+ T-cell 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 initiated a Phase 1 clinical trial of our shingles vaccine candidate, utilizing our CpG 1018 adjuvant. The Phase 1 study was designed to evaluate safety, tolerability and immunogenicity of the vaccine candidate which is comprised of glycoprotein E (gE) plus CpG 1018 adjuvant.

In January 2023, we announced the completion of a randomized Phase 1 clinical trial of our shingles vaccine program evaluating the safety, tolerability, and immunogenicity in adults. At four weeks following the 2-dose regimen, the investigational shingles vaccine Z-1018 demonstrated high antibody and CD4+ T-cell vaccine response rates in all arms, which were similar to the licensed comparator. Robust increases in CD4+ T-cells were observed in all Z-1018 arms, although lower than the comparator. Total frequency of solicited systemic adverse events and local post-injection reactions and moderate and severe reactions were similar across the Z-1018 arms and lower than the comparator.

In June 2023, we presented results from the Phase 1 trial at the National Foundation for Infectious Diseases' 2023 Annual Conference on Vaccinology Research. These results demonstrate the opportunity to develop a shingles vaccine with improved vaccine tolerability and comparable efficacy to Shingrix and support the continued development of our shingles vaccine candidate. We received Type B meeting feedback from the FDA on the Z-1018 clinical development plan and submitted an IND to the FDA to support the initiation of a Phase 1/2 trial of Z-1018, upon IND clearance, in the first half of 2024.

In June 2024, we initiated a Phase 1/2 clinical trial evaluating the safety, tolerability, and immunogenicity of Z-1018. Enrollment in the Phase 1/2 randomized, active-controlled, dose escalation, multicenter trial was completed in 2024, with approximately 440 healthy adults aged 50 to 69 years enrolled at trial sites in Australia. The trial will evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix. Key objectives of the trial include selecting the optimal glycoprotein E (gE) protein dose level and dosing schedule for further clinical development. The Phase 1/2 trial will be used to support validation of a Patient Reported Outcome measurement tool to differentiate Z-1018 on tolerability and to support potential label claims. We anticipate reporting top line immunogenicity and safety data in the third quarter of 2025.

Tdap Vaccine Program

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 CpG 1018. 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.

In October 2022, we presented adult and adolescent safety data from the Phase 1 clinical trial of Tdap-1018, which was well tolerated with no safety concerns observed. Additionally, immunogenicity levels in adults met our expectations and support our plan to continue advancement of this clinical program.

In December 2023, we completed a pertussis challenge study in nonhuman primates demonstrating protection from disease upon challenge and robust Type 1 T helper (Th1) cell responses in nonhuman primates vaccinated with Tdap-1018. After we received Type B meeting feedback from the FDA on the Tdap-1018 clinical development plan,

we evaluated the persistence of pertussis immunogenicity of Tdap-1018 through a long-term follow-up study of participants that completed a Phase 1 trial of a booster dose of Tdap-1018 compared to an active control. Based on results from this long-term follow-up study, in November 2024 we decided to discontinue development of the Tdap-1018 program as it did not demonstrate a differentiated profile that we believe would be successful commercially.

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

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 agreed to conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine designed to show that two doses of CpG 1018 adjuvanted vaccine administrated within a period of one month is similar to three doses of the aluminum-adjuvanted vaccine administered over a period of six months.

In August 2022, we commenced the Phase 2 clinical trial with the first participant dosed, evaluating the immunogenicity, safety and tolerability of the DoD’s rF1V vaccine combined with our CpG 1018 adjuvant, in adults 18 to 55 years of age.

In January 2023, Part 1 of the Phase 2 clinical trial evaluating the immunogenicity, safety, and tolerability in adults of a plague (rF1V) vaccine candidate adjuvanted with CpG 1018 was successfully completed. Both CpG 1018 adjuvanted arms met the Part 1 primary endpoint and demonstrated a greater than two-fold increase in antibodies over the alum adjuvanted control arm after two doses. In 2023, we completed enrollment and dosing in Part 2 of the Phase 2 clinical trial evaluating immunogenicity, safety, and tolerability. Preliminary results were received in 2024.

In July 2023, we executed a contract modification with the DoD to support advancement of the plague vaccine candidate into a nonhuman primate challenge study. This study was completed in 2024 and totaled $33.7 million.

In late 2024, we completed the phase 2 clinical trial evaluating the immunogenicity, safety, and tolerability in adults of a plague (rF1V) vaccine candidate adjuvanted with CpG 1018. Based on the results from that study, we executed a new agreement with the DoD for approximately $30.0 million through the first half of 2027 to support additional Phase 2 clinical and manufacturing activities.

CpG 1018 Adjuvant Supply Partnerships for COVID-19 Vaccine Development

To support the fight against COVID-19, we collaborated with five other organizations on their development of COVID-19 vaccines, by supplying them with CpG 1018 adjuvant under commercial supply agreements supported by two contract manufacturing organizations, with whom we developed and implemented plans to help scale-up activities to support pandemic-level production of our CpG 1018 adjuvant as necessary to support these and any future collaborations. As of December 31, 2022, our delivery obligations under our related supply agreements with all five organizations had been fully satisfied. Under our agreement (together with subsequent amendments, the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations (“CEPI”), through December 31, 2024, we received advance payments totaling approximately $175.0 million, of which $67.3 million have been repaid and $47.4 million have been forgiven. As of December 31, 2024 and 2023, remaining advance payments totaling $60.3 million in CEPI accrual long-term were reflected in our consolidated balance sheets. 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.

For a summary of our significant CpG 1018 adjuvant collaboration agreements, see Note 9 - Collaborative Research, Development and License Agreements, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

INTELLECTUAL PROPERTY

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our products, 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, and we rely on trademarks to protect our brand, products, product candidates, and technology.

As of December 31, 2024, our intellectual property portfolio included over 20 issued U.S. patents, over 45 granted foreign patents and over 130 additional Dynavax-solely owned or co-owned pending U.S. non-provisional and

foreign patent applications claiming compositions containing TLR agonists or antagonists, methods of use, and/or methods of manufacture thereof. Specifically, our portfolio includes: (i) three issued U.S. patents related to certain uses of HEPLISAV-B that expire in 2032; (ii) 32 pending U.S. and foreign patent applications related to an investigational shingles vaccine; (iii) four issued U.S. and foreign patents and 53 pending U.S. non-provisional and foreign patent applications related to COVID-19 vaccines, which include patent families that are either solely-owned or co-owned with Valneva Austria GmbH, Medigen Vaccine Biologics Corporation, or Colorado State University Research Foundation; and (iv) one pending U.S. patent application related to an investigational plague vaccine, which is co-owned with The Government of the United States, as Represented by the Secretary of the Army. Lastly, some of the patents and patent applications in our portfolio relate to our discontinued tetanus, diphtheria, pertussis (Tdap) booster vaccine and immuno-oncology programs.

In general, the term of a patent extends for 20 years from the filing date of the earliest U.S. non-provisional or international (PCT) application to which priority is claimed. In certain instances, a patent term may be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. Moreover, in the U.S., the term of a patent may be extended as a consequence of patent office delays during prosecution. Our patent estate, based on patents existing now and expected by us to issue based on pending applications, is projected to expire on dates ranging from 2025 to 2044.

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 post-grant 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 invalidated.

Our commercial success depends significantly on our ability to operate without infringing patents and other 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 may not be able to determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use, offer to sell, 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 they arise.

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 standard practice is to require each of our collaborators, commercial partners, employees, consultants, contractors 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 with employees, consultants and contractors 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, there are multiple other shingles vaccine candidates in development including those being developed by Pfizer, BioNTech SE, Curevo Vaccine, Moderna, Inc., and others. 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 through clinical and commercial supply agreements, 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 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, the United Kingdom 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, and PreHevbrio, a three-dose adult hepatitis B vaccine manufactured by VBI Vaccines Inc. ("VBI"). While we believe that HEPLISAV-B competes very well with other approved vaccines available on the market, we face significant competition in our longer term goal to capture a majority of U.S. market share. To the extent that we explore additional territories outside of the U.S., the EU and the United Kingdom 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 shingles, plague 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, Bavarian Nordic A/S, Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., and Johnson & Johnson.

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 U.S., 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 U.S. generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and, at a minimum, 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 ("NDA") or a biologics license application ("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 ("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, often 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 product 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 accepting the submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, eight months from accepting the submission. During the review process, the FDA often has multiple requests for information or clarifications. The review process may be extended if the FDA deems that a response contains significant new information and will require additional time beyond the period originally designated to appropriately review. 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 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, 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.

Clinical Trials in the EU. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (“CTR”), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 (“CTD”).

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal," the Clinical Trials Information System (“CTIS”); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State concerned. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD continued to apply on a transitional basis until January 31, 2025. All ongoing trials are now subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

European Union Marketing Authorization. To obtain a Marketing Authorization ("MA") for a product in the EU, an applicant must submit a Marketing Authorization Application ("MAA") either under a centralized procedure administered by the European Medicines Agency ("EMA") or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs"), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the EMA’s Committee for Medicinal Products for Human Use ("CHMP") is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMDh") for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and active pharmaceutical ingredients ("APIs"), including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. MA holders and/or manufacturing and import authorization ("MIA") holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity. The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/ biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Pediatric Development. In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC") if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Post-Approval Requirements. Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan ("RMP") describing the risk management system that a company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or

post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each Member State and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Medicinal Products in the UK and Brexit. The United Kingdom's ("UK") withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency ("MHRA") is now the UK's standalone regulator for medicinal products and medical devices. The UK is now a third country to the EU.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments, if implemented in their current form, bring the UK into closer alignment with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure.

In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applications should be decided within a maximum of (i) 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years, or (ii) 110 days if major objections are identified or such approval has not been granted within the previous 2 years. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorizations, effective in the UK only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of EU authorizations in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing

processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

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, state and foreign 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 are 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 HIPAA in the United States, the European Union's General Data Protection Regulation ("EU GDPR") in the European Economic Area ("EEA"), and the UK's General Data Protection Regulation ("UK GDPR"). New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened.

For example, the EU GDPR imposes strict requirements on the processing of personal data, which apply to non-EU entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data. The EU GDPR implements more stringent operational requirements than its predecessor legislation.

Also, the California Consumer Privacy Act of 2018 ("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, the California Privacy Rights Act ("CPRA") significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a state agency that is 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 and equivalent foreign laws that require pharmaceutical manufacturers to make reports to states and equivalent foreign authorities on pricing and marketing information. Several states and local jurisdictions and equivalent foreign laws 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. Some foreign jurisdictions, including a number of EU Member States, impose equivalent requirements. 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 and on some foreign markets 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. We are 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 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 could subject us to substantial penalties.

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. Further, coverage policies and reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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. For example, the newly elected Presidential administration may be more skeptical of the safety and efficacy of vaccine products, which could lead to increased regulatory scrutiny and more restrictive coverage policies regarding vaccine 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 foreign 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, in the US, regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

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. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law, which among other things, (1) directs the U.S. Department of Health and Human Services (“HHS”) to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under Medicare (the “Medicare Drug Price Negotiation Program”) and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, on January 5, 2024, the FDA approved Florida’s Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Additionally, 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 addition, 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 have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the second Trump administration will impact the ACA.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional Congressional action is taken. 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.

Moreover, in the EEA some countries require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") Regulation, was adopted in the EU. This HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the level of the EU for joint clinical assessments in these areas. The HTA Regulation has applied from January 12, 2025. Although it will enter into force iteratively and initially apply to new active substances to treat cancer and to all advanced therapy medicinal products (ATMPs), it will then be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Selected high-risk medical devices will also be assessed under the HTA Regulation as of 2026. The HTA Regulation is intended to harmonize the clinical benefit assessment of HTA across the EU. Pricing and reimbursement decisions, based on these assessments, remain the responsibility of individual Member States. In light of the fact that the UK has left the EU, Regulation No 2021/2282 on

HTA does not apply in the UK. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of March 31, 2025, relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

MANUFACTURING

We rely on our facility in Düsseldorf, Germany and third parties to perform the multiple processes involved in manufacturing HBsAg for use in HEPLISAV-B, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. 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 oligonucleotides for clinical trials and conduct formulation, fill and finish operations. We rely on a single supplier to produce our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators. Switching suppliers, or bringing on additional suppliers, could be complicated and time consuming, but we generally seek to maintain inventory to help bridge any unexpected gap in supply. In order to help us successfully manufacture and commercialize HEPLISAV-B, we have secured long-term supply agreements with the key third-party suppliers and vendors for commercial supply of our component products and finished goods. 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 directors, officers and 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 and Compliance." We have a Chief Ethics and Compliance Officer, a Compliance Steering Committee and policies, procedures and training addressing specific aspects of our business, including advertising and promotion; engagements with healthcare providers; and regarding our business activities outside the United States to ensure they comply with the U.S. Foreign Corrupt Practices Act and all other applicable anti-corruption laws. We certify on an annual basis to having a comprehensive compliance program that meets the standards set forth under California law. This certification, which sets forth all of the elements of our healthcare compliance program, can be found on our website.

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. Our transition to a largely virtual environment has further helped reduce congestion and pollution. Our relatively small headquarters space (approximately 8,000 square feet) has further reduced our carbon footprint. In addition, we participate in our building's 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 MANAGEMENT

As of December 31, 2024, we had 405 employees, comprised of 260 employees in the U.S., including 103 members of our field sales team located throughout the U.S., as well as 145 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 and Compensation

Our regrettable turnover rate for 2024 was 6% in the U.S. and 5% in Düsseldorf. Despite these low turnover rates, as a vaccine-focused company, we face stiff competition to hire and retain our employees. The average

tenure among our employees is 3.7 years in the U.S. and 6.1 years in Düsseldorf. We also believe that our remote-first working environment in the U.S. serves as a useful recruiting and retention tool.

We 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, which includes base salary, annual cash bonus opportunity or semi-annual sales incentive bonus for our field sales team, comprehensive benefits package and equity compensation. Each of our employees participates in our equity programs. The annual cash bonus opportunity and equity compensation generally increase as a percentage of total compensation based on level of responsibility. Any actual cash bonus payout for our employees is based on a combination of our performance against corporate goals and individual performance, with the exception of any actual cash bonus payouts to our Chief Executive Officer and President which is based solely on our performance against corporate goals. The mix of equity compensation also shifts based on the level of responsibility; employees below the senior director level typically receive 100 percent of their equity compensation in restricted stock units, while more senior level employees typically receive a mix of stock options and restricted stock units. Annual equity awards to our senior leadership team include performance-based restricted stock units.

Employee Development and Workplace Culture

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. We perform annual performance reviews of all employees, and we seek employee feedback in a variety of ways, including annual employee surveys. In 2024, 29 leaders and key contributors completed a leadership development program, in addition to the 32 who participated in the prior year. Our senior management and human resources team periodically undertake comprehensive organizational reviews. In addition, we have an extensive series of employee training programs on business ethics and compliance matters, including required annual trainings on our Code, our Anti-Corruption Compliance Policy and certain cybersecurity topics. Also, depending on employee roles and departments, we have employee training programs on medical affairs, commercial, sales and other matters.

The development and engagement of our employees is among our top priorities. We remain committed to living out our core values and in creating a culture where every employee is recognized and appreciated for the unique individuals they are. Our work related to these commitments focus on community outreach and engagement as well as efforts to support leadership excellence and career development for all employees. As a vaccine company, bettering public health is core to our mission, and that responsibility reaches to bettering the lives of our employees and broader communities.

In 2024, we were certified as a Great Place To Work for the second year in a row. In addition, we were named by Fortune as one of the Best Places to Work in small to medium sized biotech companies in the United States.

CORPORATE INFORMATION & AVAILABLE INFORMATION

Our principal executive offices are located at 2100 Powell Street, Suite 720, 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 approved in the United States, the European Union and the United Kingdom and launched in the United States and Germany, 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 United States and Germany. We have also received approval in the European Union and the United Kingdom for HEPLISAV-B. Successful commercialization of HEPLISAV-B in these regions or elsewhere will require significant resources and time, and there can be no certainty that we will succeed in these efforts. 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 through distribution, and the timing, trajectory, rate and sustainability for growth in sales is unpredictable, and we may not be successful in commercializing HEPLISAV-B in the long term. 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 have continued to expand our field sales force. As these teams expand, it will take time for our expanded teams to generate significant sales momentum, if they do so at all. Although we have had some success growing and developing our field sales force following the launch of HEPLISAV-B, there is no guarantee that we will be able to generate sales at the same or improved rates going forward, if at all. In addition, retention of capable sales personnel may be more difficult for us compared to our competitors, as we focus on a single product offering. We must retain our sales force in order for HEPLISAV-B to maintain or expand its commercial presence.

Moreover, we expect that we will need to divert resources in order to successfully market, sell and distribute HEPLISAV-B for use with dialysis patients, one of our targeted patient populations. We do not yet have approval to market the regimen for dialysis. In the second quarter of 2024, the FDA issued a Complete Response Letter ("CRL") for the supplemental Biologics License Application ("sBLA") to include a four-dose regimen for adults on hemodialysis in the U.S. label, and we are exploring approaches to address the deficiencies noted in the CRL. In the fourth quarter of 2024, we received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support our sBLA filing for adults on hemodialysis. We expect to resubmit our sBLA for HEPLISAV-B vaccination of adults on hemodialysis to the FDA in 2025. We may be unsuccessful in conducting an observational retrospective cohort study, may not successfully resubmit our sBLA for a four-dose regimen for adults on hemodialysis, and may never obtain FDA approval for such indication, which would limit our addressable market and revenue. 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 on dialysis, receive hepatitis B vaccinations, our predictions of how many of those patients actually receive HEPLISAV-B may be inaccurate. In particular, vaccine skepticism and disinformation may impact the willingness of patients to consider hepatitis B vaccination.

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 continue recruiting and retaining 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 continue to 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 sustaining a capable sales and marketing organization and related commercial infrastructure.

If we are not able to enter new markets ourselves, 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, as we have done for HEPLISAV-B distribution in Germany, the product's 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 these new markets. 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.

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 broad reimbursements and pricing approval in any European Union Member State and rely on our distributor to do so, who currently only markets in Germany. 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, the United Kingdom or elsewhere may 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., Germany and elsewhere, we will have difficulty successfully commercializing HEPLISAV-B, which would adversely affect our business and financial condition.

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.

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, 2022, we recognized $587.7 million of CpG 1018 adjuvant revenue. However, our CpG 1018 adjuvant supply agreements expired at the end of 2022, and as a result, we did not recognize CpG 1018 adjuvant revenue for the years ended December 31, 2024 and December 31, 2023. Similarly, if demand for HEPLISAV-B decreases from recent trends for any reason, that could also cause unexpected fluctuations in our quarterly and annual operating results.

The occurrence and timing of any transfer of control of product sold to customers can also be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. As an example, any future revenue we do receive from sales of our CpG 1018 adjuvant has been and will continue to be difficult to predict, if it materializes at all. Historically, we generally required customers to place orders for CpG 1018 adjuvant with at least six months lead time and to make an advance payment toward the finished order. Where we receive such advance payments, we record such payments as deferred revenue until we have delivered the adjuvant and met all criteria to recognize revenue. In accordance with our stated revenue policy, we historically recorded 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. During the year ended December 31, 2024 and December 31, 2023, we did not receive any advanced payments from any of our customers to purchase CpG 1018 adjuvant. Our collaborators in many cases have purchase agreements with government agencies. If our collaborators do not receive payment from these agencies for any past or future adjuvant orders, our ability to collect our own receivables may be adversely affected. For example, as of December 31, 2023, we had recorded an allowance for doubtful accounts of $12.3 million in connection with our accounts receivable balance due from Bio E, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to an amendment to the supply agreement with Bio E, and Bio E's dependence on cash collections from the Government of India, which have been delayed significantly by the Government of India.

We have in the past, and may in the future, adjust delivery dates, allow cancellations or give concessions on outstanding receivables in certain circumstances to better enable our customers to meet their obligations, which can impact the timing or amount of our revenue recognition, cash collections and transfer of control. For example, in August and October 2022, we entered into amendments to our Supply Agreement, dated June 29, 2021, with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (the "Clover Supply Agreement"), which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018 adjuvant deliverable under the agreement and/or reduce amounts receivable, which we originally intended to deliver in accordance with a purchase order previously issued by Clover, and apply prepayments Clover previously made to us as payment for portions of pending outstanding purchase orders. In January 2023, we entered into another amendment to the Clover Supply Agreement to modify the price per dose of CpG 1018 adjuvant paid by Clover for adjuvant used in finished vaccine doses sold through government procurement programs relating to the booster program promoted by the China National Health Commission. In addition, in April 2023, we entered into the Bio E Amendment No. 3 and the CEPI-Bio E Assignment Agreement, pursuant to which CEPI forgave amounts outstanding relating to the Bio E CEPI Advance Payments and assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Among other things, the CEPI-Bio E Assignment Agreement resulted in no accounts receivable from Bio E, the derecognition of $47.4 million

CEPI accrual in connection with the Bio E CEPI Advance Payments, and certain additional future payments contingent on Bio E's receipt of payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025, which may not materialize.

Moreover, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others due to, among other factors, revenue fluctuations or increases in expenses as we invest in our pipeline. We may also incur significant expenses in any given reporting period related to shareholder engagement matters, including, without limitation, fees for legal, financial and other professional advisors. 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 have incurred annual net losses in most years since our inception and could continue to incur significant losses if we do not successfully commercialize HEPLISAV-B, launch new products and/or significant sales of our CpG 1018 adjuvant do not resume.

Prior to January 1, 2021, we had incurred losses in each year since we commenced operations in 1996. While we recognized revenue for the years ended December 31, 2021, 2022 and 2024, we recognized a net loss of $6.4 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $903.3 million.

With our investment in the launch and commercialization of HEPLISAV-B in the United States and Germany, we have in the past, and could in the future, incur operating losses. Our expenses have increased substantially as we 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. Further, we expect to increase research and development costs as we invest in our pipeline. We are already advancing a multi-program clinical pipeline leveraging CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs including a Phase 1/2 clinical trial for shingles and additional clinical and manufacturing activities, including a Phase 2 clinical trial expected to initiate in the third quarter of 2025, for plague in collaboration with and fully funded by the U.S. Department of Defense ("DoD"). We expect research and development costs to increase further if we add additional programs to our pipeline.

Sales of CpG 1018 adjuvant generated significant revenue during the COVID-19 pandemic, but we do not currently expect such revenues to continue in the long term, and we did not recognize any CpG 1018 adjuvant revenue in the year ended December 31, 2023 nor December 31, 2024. 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 recurring basis, or, that if we are able to reach consistent profitability that it will be sustainable for any period of time.

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, GlaxoSmithKline plc ("GSK") and VBI Vaccines Inc. ("VBI"), and 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 United States, the European Union and the United Kingdom. Competition in European markets could affect our success or the success of our distributor in that market as well. In addition, HEPLISAV-B competes against Twinrix, a bivalent vaccine marketed by GSK for protection against hepatitis B and hepatitis A.

We are also in competition with companies developing vaccines and vaccine adjuvants, generally including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Bavarian Nordic A/S, Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson, VBI, BioNTech SE and Curevo Vaccine. We will likely compete with several of these companies in the hepatitis space, shingles space, and other 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 properly manage our business, obtain financing as needed, enter into collaborative arrangements, advance or sell our product candidates or generate revenues.

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 hepatitis B surface antigen for use in HEPLISAV-B, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. We may continue to do the same for any additional products we might add in the future through natural internal expansion of our pipeline, or in transactions with an external third-party or parties. The FDA approved our pre-filled syringe 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 ourselves, 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, whether because of problems with our supplier's own operations, operations of its sub-suppliers, issues with downstream supply chains or otherwise. If our contract manufacturer is unable to source components needed to complete fill and finish of our pre-filled syringes, we may be required to identify a second source which would have associated costs and regulatory requirements. Qualifying a second source could take more than a year to accomplish. If we are unable to do all this, on a timely basis or at all, our HEPLISAV-B sales could be materially and adversely impacted.

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 manufacture of HEPLISAV-B and for sale to our collaborators and (ii) our pre-filled syringe presentation. In 2021, we qualified a second supplier to manufacture CpG 1018 adjuvant for our COVID business. If we are 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 potentially 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 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.

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, collaboration partners, 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 or any new products, 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. Any failure to accomplish any of these activities could prevent us from successfully increasing or maintaining the same level of commercial growth as we have seen in the past.

If HEPLISAV-B or any products we develop are not accepted by the market or if regulatory authorities 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 future revenues, if any.

Even if we obtain regulatory approval for our product candidates, such as our U.S., European Union and the United Kingdom 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 products;
- 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 efforts;
- 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.

Market acceptance of vaccines has been negatively impacted in recent years due to increasing vaccine skepticism and disinformation. The potential for individuals with anti-vaccine views to hold governmental and other roles of influence and for disinformation campaigns to negatively impact potential market acceptance for HEPLISAV-B and any of our future approved products may slow our sales growth and weaken our market prospects.

The FDA or other regulatory authorities 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 products or product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenue could be significantly impaired.

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 in part reliant upon third parties to manufacture on our behalf.

As our commercial business begins to expand in connection with commercial sales of HEPLISAV-B or CpG 1018 adjuvant, as applicable, 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. To the extent we add new products in the future, these risks could be exacerbated by the added complexity of managing multiple product lines.

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. Reimbursement or pricing in jurisdictions outside the U.S. may be less favorable. Thus, there can be no assurance that HEPLISAV-B will achieve and sustain stable pricing and favorable reimbursement. Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market's acceptance of a price for HEPLISAV-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, the willingness of third-party payors to reimburse for our products is uncertain. We will have to charge a price for HEPLISAV-B or any other products we commercialize 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. For example, the newly elected Presidential administration may be more skeptical of the safety and efficacy of vaccine products, which could lead to increased regulatory scrutiny and more restrictive coverage policies regarding our products and product candidates. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to achieve or maintain profitability, and such unavailability could harm our future prospects and reduce our stock price.

The UK and many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in European countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and applies as of January 12, 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the UK has left the EU, Regulation No 2021/2282 on HTA does not apply in the UK. However, the UK Medicines and Healthcare products Regulation Agency (“MHRA”) is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (“SMC”), the National Institute for Health and Care Excellence (“NICE”), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products. For example, in March 2021, the UK introduced the Innovative Licensing and Access Pathway (“ILAP”) which brings together the MHRA, NICE, SMC and the All Wales Therapeutics and Toxicology Centre, to accelerate time to market for certain innovative products. The ILAP temporarily stopped accepting applications on November 20, 2024, but applications under a relaunched ILAP will reopen in March 2025, with changes including improvements to interaction with the National Health Service and an amended eligibility and selection criteria.

Legislators, policymakers and healthcare insurance funds in the EU and the UK may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that COVID-19 placed on national healthcare systems of European countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We are subject to ongoing FDA, EU and comparable foreign 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 ("AMI"). This post-marketing study was initiated in August 2018 and concluded in November 2020. While the results of the study, announced in April 2021, indicated that there was no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B, we may be required to conduct further studies on HEPLISAV-B or our other product candidates in the future. Also, we received data from the autoimmune portion of our observational study, and the data indicated no association between HEPLISAV-B and any of the studied autoimmune diseases. In addition, we conducted a pregnancy registry study to provide information on outcomes following pregnancy exposure to HEPLISAV-B and submitted the information to the FDA in December 2023. In May 2024, the FDA released us from the post-marketing commitment related to the pregnancy registry study. Failure to complete any future post-marketing obligation to the satisfaction of the FDA could result in withdrawal of our biologics license application approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. As we advance our pipeline, similar studies may be required for other candidates. The results of post-marketing studies may also result in additional warnings or precautions for the HEPLISAV-B label or labels of any future products, if authorized, or expose additional safety concerns that may result in product liability and withdrawal of a product or products 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 and the UK. For example, we are required to submit periodic safety update reports to the European Medicines Agency ("EMA") and the MHRA 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 HEPLISAV-B. In addition, in accordance with our EU marketing authorization for HEPLISAV-B, HEPLISAV-B is subject to additional monitoring, meaning that it is monitored more intensively than other medicinal products. We may have similar obligations for future products if and when approved. Non-compliance with European Union or UK 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, the European Union and the UK. 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"), International Conference on Harmonization guidelines, and good laboratory practices ("GLP"). If we are not able to meet and maintain regulatory compliance for HEPLISAV-B or any future product, if authorized, 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.

HEPLISAV-B and all of our clinical programs rely on oligonucleotide TLR agonists. In the event of serious adverse events relating to TLR agonists, we may be required to reduce the scope of, or discontinue, our operations, or reevaluate the viability of strategic alternatives.

Our programs, including HEPLISAV-B, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors or collaborators result in serious adverse events, 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 events are found to relate to our TLR agonist 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 cGMP 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 Biologics License Application ("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 is 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. Similar requirements and procedures apply outside of the United States.

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.

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 authorities 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.

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 authority requirements are expensive and time consuming, may take more time to complete than expected, may not be completed at all, 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"), Ethics Committee or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available vaccine or component supply.

Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. Failure of one or more product candidates to successfully advance through to approval and licensure could result in the loss of unrecoverable costs expended and impact our ability to generate future revenue from such products, either of which, or both of which, could have an adverse impact on our business.

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 products or product candidates and our discovery research programs. Failure to obtain a collaborative relationship for those products or product candidates and programs 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 perceived shortage of capital resources may impact the willingness of companies to collaborate with us;
- our contracts for collaborative arrangements are often 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 intellectual property or other proprietary rights 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. 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.

Even when we are successful in entering into collaboration agreements, collaborations can involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our solely-owned development and commercialization programs, and the financial terms upon which collaborators are 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.

For example, we are working to develop our CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations, partnerships and supply arrangements. Current relationships and efforts are focused on adjuvanted vaccines for COVID-19, shingles and plague. For some of these relationships, our collaborators have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval of potential vaccines 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. In circumstances where our collaborators do not purchase as much adjuvant as we anticipate or they delay placing orders or taking certain deliveries, there can be a negative impact on our revenue recognition. If a collaborator fails to conduct collaborative activities successfully, the development and commercialization of a vaccine could be delayed or may not occur at all. Lastly, the ability of our collaborators to deliver, sell and collect on receivables is not guaranteed and this could, in turn, impact our own ability to collect receivables.

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, 2024, we had $713.8 million in cash and cash equivalents, and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. While we recognized revenue for the years ended December 31, 2021, 2022 and 2024, we recognized a net loss of $6.4 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $903.3 million. 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 may 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, our 2.50% convertible senior notes due 2026 ("Convertible Notes") and other securities we issue in the future may have rights senior to those of our common stock and could include covenants that 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 disruptions to and volatility in the credit and financial markets in the United States and worldwide. 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 and the value of our stock.

As we plan for the broader commercialization of our HEPLISAV-B vaccine and for the requisite capacity to manufacture our CpG 1018 adjuvant, our financial commitments for manufacturing and supply capacity might outpace actual demand for our products.

As we manage our production capabilities for HEPLISAV-B and CpG 1018 adjuvant to support recent market share gains and other initiatives, we have been, and in the future could be, required to make significant financial commitments at our contract manufacturing organizations ("CMOs"), including minimum purchase commitments and prepayments of purchase orders to facilitate the procurement of raw materials and the incurrence of various manufacturing costs. Because of minimum or advance purchase commitments and uncertainty about the expected demand for HEPLISAV-B or CpG 1018 adjuvant, the financial commitments we make to our CMOs to support manufacturing may not be recovered in their entirety, or at all, if our customers do not ultimately purchase from us at expected volumes, or other concessions are made by 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. Similarly, prepayments of purchase orders may not be recoverable if we do not ultimately require the entire volume subject to the applicable purchase order. As a result, we could end up making financial commitments that we never recover if demand for HEPLISAV-B or CpG 1018 adjuvant does not materialize in the volumes we are expecting or at all. This may require us to record certain charges or write-offs in one or more fiscal periods, which in turn could result in significant, unexpected fluctuations in our quarterly and annual operating results, and potentially have a material adverse effect on our results of operations, and financial condition.

For example, in August and October 2022, we entered into amendments to the Clover Supply Agreement, which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018

adjuvant that we originally intended to deliver in accordance with a purchase order previously issued by Clover. As a result of the concessions made in the amendments to the Clover Supply Agreement, prior financial commitments made to certain CMOs to manufacture quantities of CpG 1018 adjuvant to fulfill the original Clover purchase order, and reduced demand for CpG 1018 adjuvant, we recorded write-offs of $13.9 million of CpG 1018 adjuvant raw materials inventory and $20.4 million of finished goods inventory during the year ended December 31, 2022. Relating to our Bio E Supply Agreement, we entered into an amendment and an assignment agreement in April 2023, pursuant to which (i) CEPI forgave the entirety of remaining amounts outstanding relating to the Bio E CEPI Advance Payments for CpG 1018 Materials allocated to Bio E and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable, (ii) we collected $14.5 million from Bio E, resulting in no accounts receivable balance as of December 31, 2024 and December 31, 2023, and (iii) we derecognized a $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. It is possible we may have similar write-offs in the future.

We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates outside of the U.S., the European Union and the United Kingdom, requiring a significant additional 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 in or outside of the U.S., the European Union and the United Kingdom. Developing, seeking regulatory approval for and marketing our product candidates in or outside of the U.S., the European Union and the United Kingdom in jurisdictions where we don't currently have approval could impose substantial costs, impose burdens on our personnel, and divert management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities 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, the European Union and the United Kingdom, 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, 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 existing regulatory approval in the United States, the European Union and the United Kingdom. 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 products or product candidates, which would impair our ability to generate revenues.

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

We rely on CROs, clinical sites and investigators for our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third-party contractors to ensure that clinical trials are conducted properly and

that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

As a biopharmaceutical company, we engage CROs to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with GCP standards and other applicable regulatory requirements could result in disqualification of the applicable clinical trial from consideration in support of approval of a potential product.

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

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign regulatory authorities, IRBs and the Ethics Committees 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 authorities 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 authorities 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 or Ethics Committee 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 product, 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 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.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

We have incurred significant net operating losses ("NOLs") during our history, and despite prior profitability, may not be able to achieve sustained profitability over the long term. Unused U.S. federal NOLs for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation enacted in 2017, as modified by legislation enacted in 2020, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the aforementioned U.S. tax law provisions.

As of December 31, 2024, we had U.S. federal and state NOL carryforwards of $293.5 million and $262.9 million, respectively. Of the $293.5 million U.S. federal NOL carryforwards, $293.1 million may be carried forward indefinitely with utilization limited to 80% of taxable income, and the remainder will begin to expire in 2025. The state NOL carryforwards will begin to expire in 2025.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as one or more stockholders or groups of stockholders who own at least 5% of our stock increasing their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards to offset its post-change income or taxes may be limited. We have experienced ownership changes as a result of shifts in our stock ownership in the past, and in the future it is possible that we may be deemed to have experienced additional ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Tax law changes could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act of 2017, the 2020 Coronavirus Aid, Relief, and Economic Security Act, and the 2022 Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of the

foregoing tax legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under past or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

We and the third parties supporting our operations are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations (or by the third parties supporting our operations) could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data we may collect about trial participants in connection with clinical trials, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA") requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely.

We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. California also recently passed a law protecting privacy of abortion-related records and other reproductive healthcare services. These laws would also apply to our employees in the respective states.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's General Data Protection Regulation ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Regulators in the United States are also increasingly scrutinizing certain personal data transfers and may impose data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

Outside the United States, certain jurisdictions have enacted data localization and cross-border data transfer laws, which could make it more difficult to transfer information across jurisdictions. In particular, the European Economic

Area ("EEA") and the U.K. have significantly restricted the transfer of personal data to the United States and other countries whose privacy and data security laws they believe not to offer an adequate level of protection. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and U.K. to the United States in compliance with law, such as the EU standard contractual clauses, the U.K.'s International Data Transfer Agreement/ Addendum and the EU-U.S. Data Privacy Framework and the U.K. extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we are unable to implement a legal mechanism to ensure that our transfers of personal data from the EEA or the U.K. are lawful, we could face adverse consequences, including increased exposure to regulatory actions, substantial fines and penalties and injunctions against processing or transferring personal data, and could be required to increase our data processing capabilities in the EEA, the U.K. or elsewhere at significant expense. Restrictions on our ability to transfer personal data from the EEA, the U.K. or elsewhere could impact our clinical trial activities in the EEA or the U.K. and limit our ability to collaborate with CROs and other third parties.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may face adverse consequences, which may include, but are not limited to, governmental enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class-related claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, civil and criminal liability and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to interruptions or stoppages in business operations (including clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry or revision or restructuring of our operations.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply or may become subject to in the future.

Our obligations related to privacy and data security are quickly changing and becoming increasingly stringent, creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may also necessitate changes to our information technologies, systems and practices and those of third parties upon which we rely. Moreover, despite our efforts, our personnel or third parties upon which we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture.

For instance, in the European Union, the second Network and Information Security Directive (Directive (EU) 2022/2555, "NIS2") entered into force on 17 January 2023 and had to be transposed into the national law of each Member State by 17 October 2024. NIS2 creates a specific legal framework for the resilience and incident response capabilities of entities operating in 18 sectors, including the health sector. As a result, companies in scope are obligated to maintain robust network and information systems security measures and report any significant incidents that might impact their operations. Companies that fail to comply with NIS2 may face significant operational disruptions, legal liabilities, and regulatory penalties of a maximum of €10 million or up to 2% of the total worldwide turnover of the preceding financial year.

Our employees and other personnel can use generative artificial intelligence ("AI") technologies, from time to time, in certain circumstances to perform portions of their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. Our use of generative AI could make it more difficult to comply with various privacy laws and other privacy obligations in the U.S. and Europe and could negatively affect our ability to protect or own certain intellectual property, any or all of which may cause us to incur significant expense, cause reputational damage, and otherwise adversely affect our business.

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, 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 knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- 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 our 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.

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

We have applied for, and in some cases have received, grants that, if and when received, may involve pricing or other restrictions.

We have applied for, and in some cases have received, grants from various charitable, philanthropic and other organizations that, if and when received, may come with certain pricing requirements, global access requirements, reporting requirements or other covenants that require us to make the funded product available worldwide and on a nondiscriminatory basis. For example, we received such an initial grant from the Bill and Melinda Gates Foundation in 2020 to help fund the potential scale-up of production of our CpG 1018 adjuvant that may be required in the event the CpG 1018 adjuvant is included in any approved and commercially available vaccine, whether a COVID-19 vaccine or otherwise. Covenants in these types of grants 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 to such requirements, may result in us not receiving some or all of the grant.

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 and amendments to certain aspects of ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how any such challenges and additional healthcare reform measures by the second Trump administration will impact the ACA and our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

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. For example, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain biologics covered under Medicare that have been on the market for at least 11 years (the "Medicare Drug Price Negotiation Program"), and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 15, 2024, HHS announced the agree-upon price of the first ten drugs that were subject to price negotiations, which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down.

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, particularly in light of the recent U.S. Presidential and Congressional elections and other equivalent foreign systems, some of which could further limit coverage and reimbursement of products, including our product candidates. For example, the newly elected Presidential administration may be more skeptical of the safety and efficacy of vaccine products, which could lead to increased regulatory scrutiny and more restrictive coverage policies regarding our products and 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.

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

In September 2021, we entered into an agreement with the DoD relating to the conduct of a clinical trial and studies in connection with the development of an improved plague vaccine. In July 2023, we entered into a contract modification with the DoD to support advancement into a nonhuman primate challenge study, and in December 2024, we entered into an agreement with the DoD to support additional Phase 2 clinical and manufacturing activities to be performed through the first half of 2027. 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 International Traffic in Arms Regulations 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. As a federal government contractor, we also maintain plans to ensure compliance with nondiscrimination and regulatory requirements for qualified employees on the basis of gender, race, disability, and veteran status. Consequently, we may be subject to executive orders and regulatory changes affecting various aspects of our

operations, including compliance with nondiscrimination plans. Any required elimination or modification of such plans in response to new executive orders could pose challenges in hiring or retaining employees, and may lead to other adverse operational impacts. Failure to comply with requirements applicable to us as a federal contractor could expose us to administrative, civil, or criminal liabilities, including fines, penalties, repayments, or suspension or debarment from eligibility for future U.S. government contracts and 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 assert that we have infringed their patents or other proprietary rights or challenge our patents or other proprietary rights, we may become involved in disputes and litigation that would be costly, time consuming and have a negative impact on the commercialization of our current products and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation or other dispute with 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 and scope 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 can cause us to incur certain legal expenses. If we become involved in any litigation and/or other administrative 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 collaborators 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 intellectual property or technologies 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, operations or financial condition.

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 may decrease, and we may be unable to realize any commercial benefit from the development of our products or product candidates.

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, if any at all. In the U.S., and worldwide, 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. Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing us and our collaborators' ability to protect our products.

Our HEPLISAV-B vaccine 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 patent claims relating to HEPLISAV-B vaccine and the use of CpG 1018 adjuvant in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to HEPLISAV-B vaccine and CpG 1018 adjuvant. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that are projected to expire in 2032. We have filed patent applications claiming compositions and methods of use of CpG 1018 adjuvant 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 adjuvant in vaccines. In addition, we are or may be subject to co-ownership of the underlying intellectual property with our collaborators and, therefore, may not be the sole owner and be in a position to diligently control patent prosecution, or enforce our rights. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize any 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 CpG 1018 adjuvant.

We also 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 or our collaborators are unable to adequately obtain, protect 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 or our collaborators 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.

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 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 post-grant 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 invalidated.

Our commercial success depends significantly on our ability to operate without infringing patents and other 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 may not be able to determine with certainty whether patents or patent applications of other parties may materially affect our ability to make, use, offer to sell, 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 they arise.

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

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 may 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;
- pending patent applications or issued patents may be challenged by third parties in litigation or other proceedings, such as inter partes reviews, pre- and post-grant oppositions, reexaminations, derivation proceedings and post-grant review, in the U.S or abroad;
- we may be subject to claims that our employees or consultants have used or disclosed trade secrets or other proprietary information of their former employers or clients, thus putting our intellectual property at risk;
- our reliance on trade secret protection and confidentiality and other agreements may not be sufficient to protect our interests and proprietary know-how related to our products and processes; and
- it may be found that we or our collaborators have not complied with various procedural, document submission, fee payment and other requirements imposed by patent offices, and our patent protection could be reduced or eliminated.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that may not be directed to what is considered to be patentable subject matter, 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 or continue to commercialize our products, enter into or maintain 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 or co-owned with 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 or any rights to the underlying intellectual property. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our products or 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 or product candidates. 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 products or 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 intellectual property (including patents), which may not be possible or could require substantial funds and time.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if

we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees or consultants may have been previously employed in other biopharmaceutical companies, including our competitors or potential competitors. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or engagements. Although no claims against us are currently pending, we may be subject to claims that these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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 standard practice is to require each of our collaborators, commercial partners, employees, consultants, contractors 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 with employees, consultants and contractors 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, which could result in substantial costs which could severely harm our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications are due to be paid to the United States Patent and Trademark Office and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdictions, and in such an event, our competitors might be able to enter the market.

We may not be able to protect our intellectual property rights throughout the world.

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 or patent claims 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. There are some countries that currently do not allow such method of use patents or patent claims, or that significantly limit the types of uses, claims or subject matter that are patentable.

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These competitor products may compete with our products and product

candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the U.S. have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO, foreign patent offices and other adjudicating bodies in granting and/or adjudicating patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our products and product candidates.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the U.S., numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights.

For example, the America Invents Act, involved significant changes in patent legislation. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations.

For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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:

- our ability to expand or retain our HEPLISAV-B vaccine market share;
- impact of COVID-19 or other respiratory or seasonal vaccination initiatives 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 authorities;
- 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, to the extent needed;
- 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;
- accumulations of our common stock or other public actions by our shareholders and related market or investor perceptions and expectations, some of which may be speculative or short term in nature;
- 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.

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. Changes in the broader macroeconomic condition, including historically high inflation, changes in interest rates, government policies, impact of pandemics or endemics and instances of geopolitical instability, such as that resulting from the conflicts in the Middle East and Ukraine, can and have caused changes in market prices, notwithstanding a lack of fundamental change in the underlying business models or prospects of companies. These broad market fluctuations have adversely affected and may in the future adversely 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 have 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 $120.0 million. As of December 31, 2024, we had $120.0 million of our common stock remaining available for future issuance under our sales agreement with Cowen & Company, LLC. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

There can be no assurance with respect to the number of shares of our common stock repurchased under the share repurchase program or that our share repurchase program will provide the benefits anticipated.

In November 2024, our Board of Directors authorized a share repurchase program to repurchase up to $200.0 million of our common stock, subject to market conditions. We can provide no assurance with respect to the number of shares of our common stock repurchased under the share repurchase program or that our share repurchase program will provide the benefits anticipated, and it may not prove to be the best use of our cash. The program could affect the trading price of our stock and increase volatility, and any announcement of a termination of this program may result in a decrease in the trading price of our stock. In addition, this program will reduce our cash reserves.

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

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

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

Our limited duration stockholder rights plan also may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that acquires beneficial ownership of more than a specified percentage of our outstanding common stock without the prior approval of our Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition, or may be redeemed by us, the rights plan may deter certain parties from pursuing strategic transactions involving us, including potential acquisitions. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder’s acquisition of our stock was approved in advance by our Board of Directors.

Risks Related to Our Outstanding Convertible Notes

Servicing our Convertible Notes 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 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 generate or 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 therefore 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.

From January 1 through December 31, 2024, the conditions allowing holders to convert all or any portion of their Convertible Notes were not met. In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be 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.

From January 1 through December 31, 2024, the conditions allowing holders to convert all or any portion of their Convertible Notes have not been met. In the event the conditional conversion feature of the Convertible Notes is triggered, the conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. 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 under the terms of the Capped Calls, 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.

We are subject to counterparty risk with respect to the capped call transactions.

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the option counterparties will not be secured by any collateral.

If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Calls with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

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, or other future products we may attempt to commercialize, 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 and achieving profitability.

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

Our business operations are subject to interruption by natural disasters and other catastrophic events beyond our control, including, but not limited to, earthquakes, hurricanes, fires, droughts, tornadoes, tsunamis, electrical blackouts, public health crises and pandemics, war, terrorism, bank failures 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 COVID-19, 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. Furthermore, during the peak of the COVID-19 pandemic there was a significantly reduced utilization of all adult vaccines (other than COVID-19 vaccines), including a reduced utilization of HEPLISAV-B.

Although we maintain inventories of HEPLISAV-B and its components, our ability and those of our contractors and distributors to produce and distribute HEPLISAV-B could be adversely affected. A pandemic or similar health challenge could severely impact the U.S. healthcare system, which may have an adverse effect on usage and sales of HEPLISAV-B. In addition, any such event could result in widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn that could affect the demand for HEPLISAV-B and future revenue and operating results and our ability to raise additional capital when needed on acceptable terms, if at all.

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

If our information technology systems or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

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, our dependence on information technology systems has intensified because many of our critical business activities are now being conducted remotely in our remote-first work environment. 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, along with those of our customers, suppliers, or third-party service providers which operate critical business systems to process sensitive information in a variety of contexts are potentially vulnerable to a variety of evolving threats and data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such threats could include, but not be limited to social-engineering attacks (including through phishing attacks), online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing or

credential harvesting), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable flaws or bugs that could result in a breach of or disruption to our information technology systems (including our products or the third-party information technology systems that support us and our goods).

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

The potential liability and associated consequences we could suffer as a result of any such cyber events could be catastrophic and result in irreparable harm including (a) the loss of trade secrets or other intellectual property, or (b) the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others, (c) extortion and other monetary damages due to malware or business email compromise, (d) significant interruptions in our operations, or (e) other significant damages. 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 EU GDPR and UK 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.

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 equivalent foreign authorities and international authorities warned businesses of increased cybersecurity threats from actors seeking to exploit the COVID-19 pandemic. If we are unable to prevent 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, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Adverse developments affecting the financial services industry may have adverse consequences on our business, financial condition and stock price.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, along with personal data and other sensitive information, including our trade secrets, data we may collect about trial participants in connection with clinical trials, and other sensitive data ("Information Systems and Data").

Our Senior Director of IT Infrastructure & Security also functions as our information security officer ("ISO"). The ISO (as part of our security function), along with our management committee and broader internal cybersecurity, IT infrastructure, and digital technology automation functions, as well as third-party service providers, all help identify, assess and manage our cybersecurity threats and risks. Our security function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, manual tools, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, coordinating with law enforcement concerning threats, responding to proactive outreach from CISA and FBI, internal and/or external audits, conducting threat assessments for internal and external threats, third-party threat assessments, conducting vulnerability assessments to identify vulnerabilities, and use of external intelligence feeds.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to help manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: a corporate security incident response plan, a vulnerability management policy, a vendor risk management program, incident detection and response processes, IT systems disaster recovery procedures, risk assessments, reasonable implementation of security controls in accordance with applicable security standards/certifications, encryption of data, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring, employee training, penetration testing, cybersecurity insurance, dedicated cybersecurity staff/officer. We also rely on third-party vendor backup/restore, disaster recovery and business continuity procedures as stated in the respective SOC 1 and SOC 2 reports if provided by such vendors as they pertain to certain of our managed services.

Our procedures for assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, (1) cybersecurity risk is evaluated as a component of our broader enterprise risk management program, identified in our risk register and monitored and managed more specifically by our Corporate Security Incident Response Team (CSIRT); (2) the security function works with the CSIRT to help prioritize our risk management processes and help mitigate cybersecurity threats that we believe are more likely to lead to a possible material impact to our business; (3) our ISO evaluates material risks identified from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors (the "Audit Committee"), which reviews and discusses with senior management our overall risk assessment and management.

We use third-party managed service providers to assist us in identifying, assessing, mitigating and managing potential risks from cybersecurity threats. In addition, we engage other advisors from time to time to help identify, assess, mitigate and manage new or developing risks in a changing threat landscape. Such ongoing services and periodic services include professional services from providers such as legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, penetration testing firms, dark web monitoring services, and forensic investigators (as needed).

We use third-party service providers to perform a variety of functions throughout our business, such as application service providers, software-as-a-service providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and other supply chain resources. We have a vendor risk management program to help manage cybersecurity risks associated with our use of these providers. This includes risk assessment for each vendor, review of security assessments, supplemental security questionnaires (as needed), security assessment calls with the vendor's security personnel, and imposition of certain information contractual obligations on the vendor. In addition, depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor risk management program may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our information technology systems or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*"

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for reviewing and discussing with management our cybersecurity risk assessment and management processes, including our oversight and the steps we take to monitor and help control risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our management, including our ISO, who has over 20 years of experience in information security. Our ISO oversees a global team of information security professionals consisting of multiple full time equivalent employees in multiple countries.

Our ISO is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our ISO (in coordination with our CSIRT) is also responsible for other functions, including preparing for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Our CSIRT reviews, approves and prioritizes information security and cybersecurity policies, projects and initiatives. Executive management is responsible for prioritizing initiatives and approving budgets to allocate funding for the foregoing based on feedback from the ISO, the CSIRT and the Audit Committee.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our ISO. The ISO works with our CSIRT to help us mitigate and remediate cybersecurity threats or incidents of which they are notified. The ISO is responsible for designing and promoting general security awareness and training, as well as defining and training relevant participants on our incident response processes. Our security and incident response processes include escalation and reporting to the CSIRT,

Disclosure and Risk Committee, senior management and Audit Committee for certain information security incidents, as warranted under the circumstances.

The Audit Committee receives periodic reports from the ISO concerning our significant cybersecurity threats and risk, and the processes we have implemented to address them. The Audit Committee also has access to various reports, summaries of reports or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2. PROPERTIES

As of December 31, 2024, the following are the material properties that we occupy:

Property Description	Location	Square Footage	Owned or Leased	Lease Expiration Date
Corporate headquarters office	Emeryville, CA	8,053	Leased	July 31, 2028
Manufacturing and office space	Düsseldorf, Germany	75,727	Leased	December 31, 2031
Laboratory and office space	Emeryville, CA	75,662	Leased (*)	March 31, 2031

(*) The entire 75,662 square feet have been subleased to a third party. Both our lease and sublease with the third party will continue until March 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 our 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 Global Select Market under the ticker symbol "DVAX."

As of February 18, 2025, there were approximately 39 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.

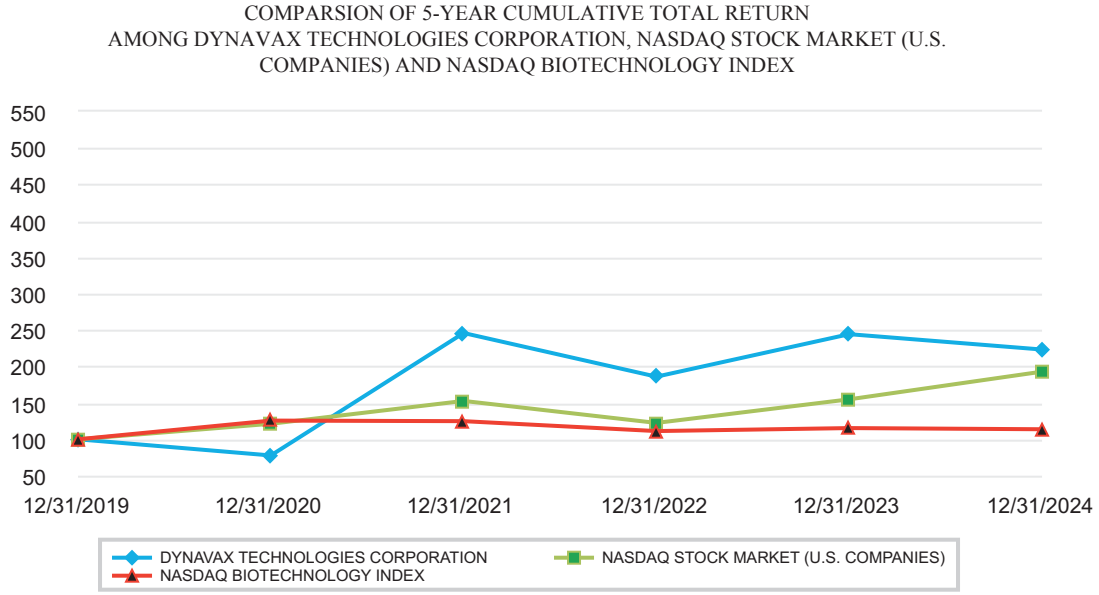
Dividends

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, 2019, 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.



ASSUMES $100 INVESTED ON DECEMBER 31, 2019
ASSUMES DIVIDENDS REINVESTED
FISCAL YEAR ENDING DECEMBER 31, 2024

	December 31, 2019	December 31, 2020	December 31, 2021	December 31, 2022	December 31, 2023	December 31, 2024
DYNAVAX TECHNOLOGIES CORPORATION	$ 100.00	$ 77.80	$ 246.00	$ 186.00	$ 244.40	$ 223.30
NASDAQ STOCK MARKET (U.S. COMPANIES)	$ 100.00	$ 121.30	$ 152.70	$ 122.50	$ 154.90	$ 192.90
NASDAQ BIOTECHNOLOGY INDEX	$ 100.00	$ 125.70	$ 124.90	$ 111.30	$ 115.40	$ 113.80

This Section is not "soliciting material," is not deemed "filed" with the Securities and Exchange Commission and is not to be incorporated by reference in 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 hereof and irrespective of any general incorporation language in any such filing.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

In November 2024, our Board of Directors authorized a share repurchase program (the "Program") allowing us to repurchase up to $200.0 million of our common stock. On November 8, 2024, we entered into an accelerated share repurchase agreement (the "ASR Agreement") with Goldman Sachs & Co. LLC ("Goldman") to repurchase an aggregate amount of $100.0 million of our common stock. Under the ASR Agreement, we made an aggregate upfront payment of $100.0 million to Goldman and received an aggregate initial delivery of 6,149,116 shares of our common stock on November 12, 2024, representing 80% of the total shares that could be repurchased under the ASR Agreement based on the closing price of our common stock on November 8, 2024. The accelerated share repurchase terminated in February 2025. As of December 31, 2024, $100.0 million remained available for future repurchases under the Program.

The following table provides information with respect to the shares of common stock repurchased by us during the three months ended December 31, 2024:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Repurchase Program (Dollars in millions)
October 1, 2024 - October 31, 2024	-	$ -	-	$ -
November 1, 2024 - November 30, 2024	6,149,116	$ 13.01	6,149,116	$ 100.0
December 1, 2024 - December 31, 2024	-	$ -	-	$ 100.0
Total	6,149,116	$ 13.01		

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 developing and commercializing innovative vaccines to help protect the world against infectious diseases. We are currently focused on our efforts to drive long-term shareholder value by maximizing utilization of our HEPLISAV-B® hepatitis B vaccine, expanding our own portfolio of innovative vaccine candidates leveraging our proven adjuvant technology, and leveraging our CpG 1018® adjuvant supply strategy through both commercial and research collaborations.

Our first marketed product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the United States, the European Union and the United Kingdom for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany.

In April 2022, the CDC's Advisory Committee on Immunization Practices ("ACIP") published its universal recommendation for hepatitis B vaccination in adults, advising that all adults aged 19-59 should be vaccinated against hepatitis B. We believe this has helped create a significantly expanded total annual market opportunity of approximately $900.0 million in the U.S. by 2030, with HEPLISAV-B expected to achieve at least 60% total market share. Additionally, we believe the HEPLISAV-B U.S. market opportunity will remain substantial beyond 2030 due to the ongoing penetration of the unvaccinated eligible adult population, observed revaccination practices by healthcare providers, and continued gains in market share. Our annual revenue has continued to grow significantly since the recommendation was made, as a result of our successful efforts to capture a greater share of an expanding market.

We are advancing a pipeline of differentiated product candidates that leverage our CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs. These programs include vaccine candidates under development for shingles and plague and additional vaccine programs in preclinical development. Additionally, we are working to advance product candidates utilizing our CpG 1018 adjuvant through discovery efforts and preclinical and clinical collaborations with third-party research organizations.

In addition, we manufacture and have supplied in the past, and could supply in the future, our CpG 1018 adjuvant to a number of global customers, including companies engaged in the development and manufacture of COVID-19 vaccines across a variety of vaccine platforms utilizing CpG 1018 adjuvant. While we did not recognize any CpG 1018 adjuvant revenue in 2024, we could see new demand in the future if our collaborators work through their inventory on hand and need additional supply, or new programs utilizing our adjuvant advance to later stages up to and including commercialization. However, long-term demand for CpG 1018 adjuvant supporting COVID-19 or other vaccines will be highly dependent on each customer's ability to commercialize in respective territories and geographies where their respective COVID-19 or other vaccines are approved for use.

HEPLISAV-B® Vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted]

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., the European Union and the United Kingdom.

We have worldwide commercial rights to HEPLISAV-B and we market it in the United States and the European Union. There are four other vaccines approved for the prevention of hepatitis B in the U.S.: Engerix-B and

Twinrix® from GlaxoSmithKline plc, Recombivax-HB® from Merck & Co and PreHevbrio™ from VBI Vaccines Inc. In February 2021, we received Marketing Authorization of HEPLISAV-B from the European Commission for prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 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 in May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. In March 2023, we received marketing authorization in the United Kingdom for HEPLISAV-B for the active immunization against hepatitis B virus infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

All of our HEPLISAV-B sales in the U.S. are to certain wholesalers and specialty distributors whose principal customers include independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Department of Defense, the Department of Veterans Affairs and retail pharmacies. All of our HEPLISAV-B sales in Germany are to one distributor. For the year ended December 31, 2024, HEPLISAV-B product revenue, net was $268.4 million.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

In January 2021, we entered into an agreement (together with subsequent amendments, 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 to the CEPI Agreement. The CEPI 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 (the “Advance Payments”) of up to $176.4 million.

Through December 31, 2024, we have received Advance Payments totaling approximately $175.0 million pursuant to the CEPI Agreement, of which $67.3 million have been repaid and $47.4 million have been forgiven (as discussed below). As of December 31, 2024, remaining Advance Payments totaling $60.3 million were reflected in CEPI accrual long-term in our consolidated balance sheets, representing the outstanding balance of the Advance Payments relating to the Clover Supply Agreement (as defined and discussed below).

In June 2021, we entered into an agreement (together with subsequent amendments, the “Clover Supply Agreement”) with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (collectively, “Clover”) for the commercial supply of CpG 1018 adjuvant, for use with its protein-based COVID-19 vaccine candidate, SCB-2019. Under the Clover Supply Agreement, Clover 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. In 2022 and 2023, we signed four amendments to the Clover Supply Agreement. The terms and conditions of the Clover Supply Agreement were operative through December 31, 2022, and as of December 31, 2022, we had satisfied all delivery obligations thereunder.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay us 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.

Approximately $71.3 million relating to future amounts receivable representing a contract asset from Clover in connection with the CEPI Agreement are classified as other assets (long term) as of December 31, 2024. The classification as long term reflects the timing of expected utilization of CpG 1018 adjuvant for Clover Product expected to be sold under the CEPI Agreement. Corresponding Advance Payments of $60.3 million relating to Clover are recorded in CEPI accrual long-term in our consolidated balance sheets as of December 31, 2024. These Advance Payments may be repaid using cash collected from Clover or forgiven in accordance with the CEPI Agreement. We had no accounts receivable balance from Clover as of December 31, 2024 and 2023.

In July 2021, we entered into an agreement (together with subsequent amendments, 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 previously 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. 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 June 2022 and October 2022, we entered into two amendments to the Bio E Supply Agreement (the “Bio E Amendment No. 1” and the “Bio E Amendment No. 2,” respectively, together the “Bio E Amendments”). The Bio E Amendments primarily established: (i) a

new payment schedule for certain outstanding invoices related to the CEPI product to be the earlier of December 31, 2022, or receipt of certain amounts by Bio E from the Government of India in connection with their advance purchase agreement for CORBEVAX, and (ii) further modified the scope of the Bio E Supply Agreement, by reducing certain quantities of CpG 1018 adjuvant to be delivered. The terms and conditions of the Bio E Supply Agreement were operative through December 2022, and as of December 31, 2022, we had satisfied all delivery obligations thereunder.

As of December 31, 2024 and 2023, we had no accounts receivable balance from Bio E. During the first quarter of 2023, we recorded an allowance for doubtful accounts of $12.3 million, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3 (defined below), and Bio E's dependence on cash collections from the Government of India, which have been delayed and significantly reduced in connection with the overall reduction in demand for CORBEVAX from the Government of India.

On April 26, 2023, we entered into a third amendment to the Bio E Supply Agreement (the "Bio E Amendment No. 3"), and on April 27, 2023, we entered into the waiver and second amendment to the CEPI Agreement by and between us and CEPI (the "CEPI-Bio E Assignment Agreement"). Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to a liability for Advance Payments of $47.4 million (the "Bio E CEPI Advance Payments") for CpG 1018 Materials allocated to Bio E, and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Pursuant to the Bio E Amendment No. 3, we collected $14.5 million from Bio E (including $13.5 million in April 2023 and $1.0 million in August 2023). Accordingly, as of December 31, 2024, the CEPI-Bio E Assignment Agreement resulted in: (i) no accounts receivable balance, and (ii) the derecognition of $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

See Note 9 - Collaborative Research, Development and License Agreements, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

Convertible Notes

In May 2021, we issued $225.5 million aggregate principal amount of 2.5% convertible senior notes due in 2026 (the "Convertible Notes") in a private placement. 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 our previous loan agreement with CRG Servicing LLC ("Loan Agreement") and $27.2 million of the net proceeds to pay the costs of capped call transactions (the "Capped Calls").

In connection with the issuance of the Convertible Notes, we entered into the Capped Calls with one of the initial purchasers and other financial institutions, totaling $27.2 million. 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 under the terms of the Capped Calls. The Capped Calls are freestanding and are considered separately exercisable from 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.

Seasonality

HEPLISAV-B is currently our only revenue-producing product. We believe that HEPLISAV-B product revenue is, and will likely continue to be, subject to seasonal variations. Specifically, HEPLISAV-B product revenue has generally been, and will likely continue to be, lower in the fourth quarter of our fiscal year compared to the third quarter due to holiday schedules and increased focus by healthcare providers on respiratory disease vaccines, including vaccines for influenza, COVID-19 and respiratory syncytial virus, during the fall and winter months.

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 - Summary of Significant Accounting Policies, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of 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 at net sales prices when control of the promised goods is transferred to the customer, incorporating 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.

Inventories

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

Recent Accounting Pronouncements

See Note 2 – Summary of Significant Accounting Policies, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on 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 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 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 our Annual Report on Form 10-K for the year ended December 31, 2023.

Revenues

Revenues consist of amounts earned from product sales and other revenues. Product revenue, net, consists of sales of HEPLISAV-B.

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. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contracts.

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 2023 to 2024	
Revenues:	**2024**	**2023**	**$**	**%**
HEPLISAV-B	$ 268,430	$ 213,295	$ 55,135	26 %
Total product revenue, net	268,430	213,295	55,135	26 %
Other revenue	8,816	18,989	(10,173)	(54)%
Total revenues	$ 277,246	$ 232,284	$ 44,962	19 %

HEPLISAV-B product revenue increased by $55.1 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. Approximately $40.3 million of the increase was due to higher volume driven by continued improvement in market share, particularly in the integrated delivery networks and retail segments, and growth in the U.S. hepatitis-B vaccine market related to the Advisory Committee on Immunization Practices ("ACIP") universal recommendation. Approximately $14.8 million of the increase was due to higher net sales price.

Other revenue primarily includes revenue from our agreement with the DoD. During the years ended December 31, 2024 and 2023, we recognized $8.6 million and $17.6 million of revenue from our agreement with the DoD, respectively. The decrease in other revenue was due to the completion of the plague Phase 2 clinical trial during the third quarter of 2024, as compared to higher revenue earned in early 2023 in connection with the initiation of Part 2 of the plague Phase 2 clinical trial.

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 HEPLISAV-B.

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

	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
Cost of Sales - Product:	**2024**	**2023**	**$**	**%**
HEPLISAV-B	$ 49,445	$ 50,167	$ (722)	(1)%
Total cost of sales - product	$ 49,445	$ 50,167	$ (722)	(1)%

HEPLISAV-B cost of sales-product decreased by $0.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was primarily due to lower per-unit manufacturing costs as a result of previous process improvements and lower comparative one-time charges, partially offset by the increase in HEPLISAV-B sales volume.

Research and Development Expenses

Research and development expenses are tracked on a program-by-program basis and consist primarily of costs incurred for the continued research and development of HEPLISAV-B and CpG 1018 adjuvant, clinical product candidates and preclinical studies, which include but are not limited to, compensation and related personnel costs (which include benefits, recruitment and travel costs), expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical studies and costs associated with our preclinical activities, including engineering activities at our manufacturing facility in Düsseldorf related to functional improvements of our product and process advances, development activities and regulatory operations. We do not allocate stock-based compensation or facility expenses to specific programs because these costs are deployed across multiple programs.

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

	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
Program Expenses:	**2024**	**2023**	**$**	**%**
Shingles	19,880	14,252	5,628	39%
Tdap	4,121	6,620	(2,499)	(38)%
Plague [(1)]	4,020	8,319	(4,299)	(52%)
HEPLISAV-B and CpG 1018 adjuvant development	5,183	5,626	(443)	(8%)
Other	13,759	8,210	5,549	68%
Other Research and Development Expenses:				
Facility costs	2,738	2,574	164	6%
Non-cash stock-based compensation	11,849	9,285	2,564	28%
Total research and development	$ 61,550	$ 54,886	$ 6,664	12%

(1) In September 2021, we entered into an agreement with the DoD for the development of a recombinant plague vaccine utilizing CpG 1018 adjuvant. Under the agreement, we conducted a Phase 2 clinical trial and studies combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. We are being fully reimbursed by the DoD for the costs of this study which is recorded in other revenue in our consolidated statements of operations.

Research and development expenses increased by $6.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023.

- Shingles program costs increased primarily due to increased clinical expenses related to the initiation of a Phase 1/2 clinical trial and the completion of patient enrollment in the study in the fourth quarter of 2024.
- Tdap program costs decreased, as we completed the long-term Phase 1 extension study in the third quarter of 2024. In connection with the discontinued development of the Tdap-1018 program announced in November 2024, we do not expect to incur significant research and development expenses for this program in the future.
- Plague program costs decreased with the completion of the Phase 2 clinical trial in the third quarter of 2024, as compared to higher costs incurred in early 2023 due to the initiation of Part 2 of the Phase 2 clinical trial.
- HEPLISAV-B and CpG 1018 adjuvant development costs decreased due to the non-recurrence of a $1.1 million expense related to an engineering run performed for product testing purposes in 2023, partially offset by continued investment in clinical research and collaboration.
- Other program costs increased as we continued to invest in product candidates utilizing our CpG 1018 adjuvant through discovery and preclinical efforts, including external collaborations.
- Non-cash stock-based compensation expense increased primarily due to incremental headcount to support the advancement of our clinical vaccine programs.

As we continue to progress our clinical-stage pipeline, we expect research and development expenses to continue to represent a substantial portion of our expenses and to continue to increase, both in dollar amount and proportion of total expense, in future years.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist 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, insurance, and 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 2023 to 2024	
Selling, General and Administrative:	**2024**	**2023**	**$**	**%**
Compensation and related personnel costs	$ 69,978	$ 63,937	$ 6,041	9%
Outside services	56,268	51,355	4,913	10%
Facility costs	8,723	8,585	138	2%
Non-cash stock-based compensation	35,405	29,069	6,336	22%
Total selling, general and administrative	$ 170,373	$ 152,946	$ 17,427	11%

Selling, general and administrative expenses increased by $17.4 million for the year ended December 31, 2024 compared to the year ended December 31, 2023.

- Compensation and related personnel costs and non-cash stock-based compensation costs increased due to continued investments in headcount and personnel across commercial and administrative functions to support HEPLISAV-B and pipeline growth.
- Outside services increased primarily due to continued investments in commercial efforts designed to increase HEPLISAV-B market share.

We expect our selling, general, and administrative expenses to remain consistent in future periods as we continue to support the overall growth of our business.

Bad Debt Expense

We did not record bad debt expense during the year ended December 31, 2024. We recorded $12.3 million of bad debt expense during the year ended December 31, 2023 in connection with the allowance for doubtful accounts of $12.3 million recorded with respect to outstanding accounts receivable from Bio E and relating to CpG 1018 Materials delivered under the Bio E Supply Agreement and CEPI Agreement. The allowance for doubtful accounts was determined by assessing changes in Bio E’s credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3, and Bio E's dependence on cash collections from the Government of India, which have been delayed significantly by the Government of India.

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 of our Convertible Notes. Sublease income is recognized in connection with our sublease of office and laboratory space.

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

	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
	2024	2023	$	%
Interest income	$ 36,464	$ 31,993	$ 4,471	14%
Interest expense	$ (6,794)	$ (6,757)	$ 37	1%
Sublease income	$ 5,014	$ 7,577	$ (2,563)	(34%)
Other	$ 293	$ (152)	$ 445	(293%)

- Interest income increased due to higher yields and balances in our marketable securities portfolio.
- The decrease in sublease income is primarily due to the recognition of a net loss of $3.5 million during the first quarter of 2024 in connection with a sublease termination, offset by sublease income of $8.5 million during the year ended December 31, 2024.

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 2023 to 2024	
	2024	2023	$	%
Income tax expense	$ 3,546	$ 2,022	$ 1,524	75 %
Effective income tax rate	11.5 %	(46.3)%	—	—

Income tax expense increased by $1.5 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. Our income tax expense of $3.5 million and $2.0 million for the years ended December 31, 2024 and 2023, respectively, are primarily comprised of state and foreign income tax expense. Our effective tax rate for the years ended December 31, 2024 and 2023 was 11.5% and (46.3)%, respectively, which is primarily comprised of state and foreign income tax expense.

Liquidity and Capital Resources

As of December 31, 2024, we had $713.8 million in cash and 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 and cash equivalents, and short-term marketable securities as of December 31, 2024, and anticipated revenues from HEPLISAV-B will be sufficient to fund our operations for at least the next 12 months from the date of this filing and in the longer term.

Advanced payments received from CEPI to reserve a specified quantity of CpG 1018 adjuvant 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, 2024 and 2023, we had no CEPI-related net accounts receivable relating to Bio E. CEPI-related accruals and contract assets relating to Clover totaled $60.3 million and $71.3 million as of December 31, 2024 and 2023, respectively. As of December 31, 2024, the CEPI-related accrual relating to Clover may be repaid using cash to be collected from Clover or forgiven in accordance with the CEPI Agreement.

In November 2024, our Board of Directors authorized the Program allowing us to repurchase up to $200.0 million of our common stock. On November 8, 2024, we entered into an accelerated share repurchase agreement (the "ASR Agreement") with Goldman Sachs & Co. LLC ("Goldman") to repurchase an aggregate amount of $100.0 million of our common stock. Under the ASR agreement, we made an aggregate upfront payment of $100.0 million to Goldman and received an aggregate initial delivery of 6,149,116 shares of our common stock on November 12, 2024, representing approximately 80% of the total shares that would be repurchased under the ASR Agreement measured based on the closing price of our common stock on November 8, 2024.

The final number of shares that we ultimately repurchased pursuant to the ASR Agreement will be based on the average of the daily volume-weighted average price ("VWAP") per share of our common stock during the repurchase period, subject to adjustments pursuant to the terms and conditions of the ASR Agreement. The accelerated share repurchase terminated in February 2025.

As of December 31, 2024, $100.0 million remained available for future repurchases under the Program. See Note 14 - Stockholder's Equity, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

On April 26, 2023, we entered into the Bio E Amendment No. 3, and on April 27, 2023, we entered into the CEPI-Bio E Assignment Agreement. Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to the Bio E CEPI Advance Payments for CpG 1018 Materials allocated to Bio E and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. The CEPI-Bio E Assignment Agreement resulted in no accounts receivable balance from Bio E. Pursuant to the Bio E Amendment No. 3, we collected $13.5 million from Bio E in April 2023 and subsequently collected the remaining $1.0 million in August 2023. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

As of December 31, 2024, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $1.6 million. The Convertible Notes bear interest at a rate of 2.5% per year, payable semiannually in arrears on May 15 and November 15 of each year. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date. See Note 10 – Convertible Notes, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

We entered into an at-the-market Sales Agreement with Cowen and Company, LLC (“Cowen”) on August 6, 2020 and an amendment to such agreement on August 3, 2023 (the sales agreement as amended, the “ATM Agreement”). Under the ATM Agreement, 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 $120.0 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 ATM Agreement. As of December 31, 2024, we had approximately $120.0 million remaining under the ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the year ended December 31, 2024, we recorded a net income of $27.3 million. For the year ended December 31, 2023, we recorded a net loss of $6.4 million. We cannot be certain that sales of our products, and the revenue from our other activities will be sustainable. Further, we expect to continue to incur substantial expenses as we continue investing in commercialization of HEPLISAV-B, advancing our research and development pipeline, and investing in 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 interest 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 or at all. 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. 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.

During the year ended December 31, 2024, we generated $66.5 million of cash from our operations, which consisted of a net income of $27.3 million, $55.2 million of net adjustments from non-cash items, which included depreciation and amortization, amortization of right-of-use assets, inventory write off, sublease termination loss, amortization of premiums (accretion of discounts) on marketable securities, stock-based compensation expense, non-cash interest expense, and approximately $16.0 million net changes from operating assets and liabilities, which included an

increase of $19.9 million in inventories primarily related to higher number of batches produced, an increase of $3.1 million in prepaid assets and other current assets primarily related to interest receivable, prepaid taxes, and prepaid insurance, a decrease of $4.4 million in lease liabilities, and an increase of $11.0 million in accrued and other liabilities. By comparison, during the year ended December 31, 2023, we generated $100.6 million of cash from our operations, which consisted of a net loss of $6.4 million, $46.7 million of net adjustments from non-cash items, which included depreciation and amortization, amortization of right-of-use assets, amortization of premiums (accretion of discounts) on marketable securities, stock-based compensation expense, non-cash interest expense, bad debt expense, and approximately $61.2 million net changes from operating assets and liabilities, which included a decrease of $43.3 million in accounts and other receivables, net and a increase of $19.8 million in accrued and other liabilities. Overall, cash provided by our operations during the year ended December 31, 2024 decreased by $34.1 million compared to the same period in December 31, 2023. 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, 2024, net cash used in investing activities was $18.0 million compared to $153.9 million of cash used in investing activities for the year ended December 31, 2023. Cash used in investing activities during the year ended December 31, 2024 included $11.7 million of net purchases of marketable securities, compared to $150.8 million of net purchases of marketable securities for the year ended December 31, 2023.

During the year ended December 31, 2024, net cash used in financing activities was $102.0 million compared to $1.4 million of cash provided by financing activities for the year ended December 31, 2023. Cash used in financing activities for the year ended December 31, 2024 included $100.0 million payment for the repurchase of common stock in connection with our ASR Agreement, $9.3 million for the payments of taxes related to net share settlement of restricted stock units ("RSUs"), partially offset by proceeds received from the exercise of options and from share purchases under our employee stock purchase plan for $7.3 million combined. Cash used in financing activities for the year ended December 31, 2023 included $6.5 million for the payments of taxes related to net share settlement of restricted stock units ("RSUs"), partially offset by proceeds received from the exercise of options and from share purchases under our employee stock purchase plan for $7.9 million combined.

Contractual Obligations

We lease our facilities in Emeryville, California and Düsseldorf, Germany. We lease and sublease certain manufacturing and office space with lease terms ranging from 3 to 12 years. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include renewal options at our election to renew or extend the lease for two successive five-year terms. These optional periods have not been considered in the determination of the Right-of-use (“ROU”) assets or lease liabilities associated with these leases as we did not consider the exercise of these options to be reasonably certain.

In December 2024, we entered into the first amendment of our headquarters office space lease (the "lease amendment") located at 2100 Powell Street, Emeryville, California, The lease amendment extends the term of the original lease by 36 months to July 31, 2028. The base rent is approximately $0.3 million for the first 12 months, including a four-month abatement, and scheduled annual 3% increases. The lease includes a renewal option.

We also sublease one of our leased premises to a third party. Rent is subject to scheduled annual increases and the subtenant is responsible for certain operating expenses and taxes throughout the life of the sublease. The sublease term expires on March 31, 2031, unless earlier terminated, concurrent with the term of our lease. The subtenant has no option to extend the sublease term. Sublease income was $5.0 million, $7.6 million and $7.7 million for the years ended December 31, 2024, 2023 and 2022, respectively. Sublease income is included in other income (expense) in our consolidated statements of operations. 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.

On February 22, 2024, our third-party subtenant obtained the approval of a voluntary petition for relief under Chapter 11 of the United States Code. As a consequence, the sublease agreement with that third-party for the subleased premises (approximately 75,662 square feet of office/laboratory space located at 5959 Horton Street, Emeryville, California) was terminated effective March 7, 2024. Simultaneously, on March 7, 2024, we entered into a new sublease agreement with a different third-party under similar conditions and for the same premises. See Note 8 - Commitments and Contingencies, in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

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, 2024, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $1.6 million. The Convertible Notes bear interest at a rate of 2.5% 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.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B. In November 2013, we entered into a Commercial Manufacturing and Supply Agreement with Baxter Pharmaceutical Solutions LLC ("Baxter") that was amended in September 2021 and January 2025 (as amended, the "Baxter Agreement"). Baxter provides formulation, fill and finish services and produces HEPLISAV-B for commercial use. Pursuant to the Baxter Agreement, we are obligated to purchase an annual minimum number of batches of HEPLISAV-B through December 31, 2029, and there are certain limits on the number of batches that Baxter is required to produce. As of December 31, 2024, our aggregate minimum commitment under the Baxter Agreement was $17.0 million within the next 12 months, and $55.4 million beyond the next 12 months.

On September 7, 2023 (the "Effective Date"), we entered into an agreement (the "Avecia Supply Agreement") with Nitto Denko Avecia Inc. ("Avecia") for the manufacture and supply of our CpG 1018 adjuvant using a specific production process. Under the Avecia Supply Agreement, Avecia has agreed to produce and supply to us quantities of CpG 1018 adjuvant ordered by us after the Effective Date. Subject to certain conditions in the Avecia Supply Agreement, we are obligated to purchase all of our annual volume requirements of CpG 1018 adjuvant from Avecia up to a specified production capacity. We may alternatively order CpG 1018 adjuvant produced using a different production process pursuant to the existing supply agreement between us and Avecia dated October 1, 2012 (the "2012 Agreement"). As of December 31, 2024, our aggregate minimum commitment for the supply of CpG 1018 adjuvant under the Avecia Supply Agreement was $8.2 million for the 12 months following December 31, 2024.

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 typically terminable by us upon reasonable written notice. Generally, we are only obligated to pay for actual time spent and materials consumed by the organizations at any point in time during the contract through the notice period.

During 2004, we established a letter of credit with Deutsche Bank as security for our Düsseldorf lease in the amount of €0.20 (Euros). The letter of credit remained outstanding through December 31, 2024 and was collateralized by a certificate of deposit for €0.2 (Euros), which has been included in restricted cash in the consolidated balance sheets as of December 31, 2024.

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 $50.0 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 our immune-oncology compound, SD-101. In July 2020, we sold assets related to SD-101 to Surefire Medical, Inc. d/b/a TriSalus Life Sciences ("TriSalus"). We paid $2.5 million to Holdings in August 2020. In each of September 2021, May 2022 and September 2023, we received $1.0 million from TriSalus because it met pre-commercialization milestones. We recorded the proceeds as gain on sale of assets in our consolidated statements of operations. We paid Holdings $0.5 million in each of September 2021, May 2022 and October 2023. We included the payments in selling, general and administrative expenses in our consolidated statements of operations. No liability has been recorded under this agreement as of December 31, 2024.

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 highly liquid investments in 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 $9.0 million or $12.0 million as of December 31, 2024, compared to $7.0 million or $9.0 million as of December 31, 2023, 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, Dynavax India LLP, and a branch of Dynavax registered in Italy, with exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of December 31, 2024 and 2023 was a $5.3 million and $3.0 million loss, respectively, primarily related to the translation of Dynavax GmbH assets, liabilities and operating results from Euros to U.S. dollars. As of December 31, 2024 and 2023, 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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 20, 2025 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 account or disclosure to which it relates.

Reserves for returns on product revenue

Description of the Matter	During the year ended December 31, 2024, the Company's net product revenues for HEPLISAV-B were $268.4 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 the estimated returns on product sales 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 and the assumptions about the estimated returns on product sales. 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 the Company's rights of return policy, obtained written representations from members of the commercial and market access 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 and 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. 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 20, 2025

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 95,883	$ 150,279
Marketable securities available-for-sale	617,951	592,023
Accounts receivables, net of allowance for doubtful accounts of $12,313 at December 31, 2024 and December 31, 2023, respectively	45,281	40,607
Other receivables	1,625	3,926
Inventories	70,054	53,290
Prepaid expenses and other current assets	18,147	18,995
Total current assets	848,941	859,120
Property and equipment, net	39,001	37,297
Operating lease right-of-use assets	21,608	24,287
Goodwill	1,946	2,067
Other assets (Note 9)	74,760	74,325
Total assets	$ 986,256	$ 997,096
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,061	$ 5,245
Accrued research and development	4,310	2,982
Accrued liabilities (Note 7)	61,066	49,448
Other current liabilities	4,197	4,520
Total current liabilities	78,634	62,195
Convertible Notes, net of debt discount of $1,646 and $2,802 at December 31, 2024 and December 31, 2023, respectively (Note 10)	223,854	222,698
Long-term portion of lease liabilities	26,388	29,720
CEPI accrual long-term (Note 9)	60,337	60,337
Other long-term liabilities	244	74
Total liabilities	389,457	375,024
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value, 5,000 shares authorized at December 31, 2024, and 2023; zero shares outstanding at December 31, 2024 and 2023	-	-
Common stock: $0.001 par value; 278,000 shares authorized at December 31, 2024 and 2023; 125,450 shares and 129,530 shares issued and outstanding at December 31, 2024 and 2023, respectively	125	130
Additional paid-in capital	1,504,671	1,554,634
Accumulated other comprehensive loss	(4,722)	(2,108)
Accumulated deficit	(903,275)	(930,584)
Total stockholders' equity	596,799	622,072
Total liabilities and stockholders' equity	$ 986,256	$ 997,096

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
Product revenue, net	$ 268,430	$ 213,295	$ 713,645
Other revenue	8,816	18,989	9,038
Total revenues	277,246	232,284	722,683
Operating expenses:			
Cost of sales - product	49,445	50,167	262,153
Research and development	61,550	54,886	46,600
Selling, general and administrative	170,373	152,946	131,408
Gain on sale of assets (Note 8)	-	(1,000)	(1,000)
Bad debt expense (Note 9)	-	12,313	-
Total operating expenses	281,368	269,312	439,161
(Loss) income from operations	(4,122)	(37,028)	283,522
Other (expense) income:			
Interest income	36,464	31,993	7,912
Interest expense	(6,794)	(6,757)	(6,732)
Sublease income	5,014	7,577	7,685
Change in fair value of warrant liability (Note 14)	-	-	1,801
Other	293	(152)	111
Net income (loss) before income taxes	30,855	(4,367)	294,299
Provision for income taxes	(3,546)	(2,022)	(1,143)
Net income (loss)	$ 27,309	$ (6,389)	$ 293,156
Undistributed earnings allocated to participating securities	-	-	(283)
Net income (loss) allocable to common stockholders	$ 27,309	$ (6,389)	$ 292,873
Net income (loss) per share allocable to common stockholders			
Basic	$ 0.21	$ (0.05)	$ 2.32
Diluted	$ 0.20	$ (0.05)	$ 1.97
Weighted-average shares used in computing net income (loss) per share allocable to common stockholders:			
Basic	130,047	128,733	126,398
Diluted	133,344	128,733	150,797

See accompanying notes.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	Year Ended December 31,		
	2024	2023	2022
Net income (loss)	$ 27,309	$ (6,389)	$ 293,156
Other comprehensive (loss) income, net of tax:			
Change in unrealized (loss) gain on marketable securities available-for-sale	(244)	2,251	(1,407)
Cumulative foreign currency translation adjustments	(2,370)	1,079	(1,765)
Total other comprehensive (loss) income	(2,614)	3,330	(3,172)
Total comprehensive income (loss)	$ 24,695	$ (3,059)	$ 289,984

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, 2021	122,945	$ 123	-	$ -	$ 1,441,868	$ (2,266)	$ (1,217,351)	$ 222,374
Issuance of common stock upon exercise of stock options	1,194	2	-	-	9,638	-	-	9,640
Issuance of common stock upon release of restricted stock awards	1,432	1	-	-	(1)	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	154	-	-	-	1,430	-	-	1,430
Issuance of common stock upon exercise of warrants	1,879	2	-	-	24,668	-	-	24,670
Stock compensation expense	-	-	-	-	32,915	-	-	32,915
Total other comprehensive loss	-	-	-	-	-	(3,172)	-	(3,172)
Net income	-	-	-	-	-	-	293,156	293,156
Balances at December 31, 2022	127,604	$ 128	-	$ -	$ 1,510,518	$ (5,438)	$ (924,195)	$ 581,013
Issuance of common stock upon exercise of stock options	850	1	-	-	6,360	-	-	6,361
Issuance of common stock upon release of restricted stock awards, net of statutory tax withholdings	915	1	-	-	(6,371)	-	-	(6,370)
Issuance of common stock under Employee Stock Purchase Plan	161	-	-	-	1,535	-	-	1,535
Stock compensation expense	-	-	-	-	42,592	-	-	42,592
Total other comprehensive income	-	-	-	-	-	3,330	-	3,330
Net loss	-	-	-	-	-	-	(6,389)	(6,389)
Balances at December 31, 2023	129,530	$ 130	-	$ -	$ 1,554,634	$ (2,108)	$ (930,584)	$ 622,072
Issuance of common stock upon exercise of stock options	684	-	-	-	5,529	-	-	5,529
Issuance of common stock upon release of restricted stock awards, net of statutory tax withholdings	1,200	1	-	-	(9,306)	-	-	(9,305)
Issuance of common stock under Employee Stock Purchase Plan	185	-	-	-	1,760	-	-	1,760
Repurchase of common stock	(6,149)	(6)	-	-	(100,565)	-	-	(100,571)
Stock compensation expense	-	-	-	-	52,619	-	-	52,619
Total other comprehensive loss	-	-	-	-	-	(2,614)	-	(2,614)
Net income	-	-	-	-	-	-	27,309	27,309
Balances at December 31, 2024	125,450	$ 125	-	$ -	$ 1,504,671	$ (4,722)	$ (903,275)	$ 596,799

See accompanying notes.

DYNAVAX TECHNOLOGIES CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating activities			
Net income (loss)	$ 27,309	$ (6,389)	$ 293,156
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	4,627	4,342	3,812
Amortization of right-of-use assets	3,425	2,934	2,856
Inventory write-off	3,144	-	34,288
Sublease termination loss (Note 8)	4,814	-	-
Amortization of premiums (accretion of discounts) on marketable securities	(14,545)	(16,555)	(4,181)
Change in fair value of warrant liability	-	-	(1,801)
Stock-based compensation expense	52,619	42,592	32,915
Non-cash interest expense	1,156	1,120	1,088
Gain on sale of assets	-	(1,000)	(1,000)
Bad debt expense (Note 9)	-	12,313	-
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(2,373)	43,268	(15,699)
Inventories	(19,909)	3,909	(32,399)
Prepaid manufacturing	-	-	159,655
Prepaid expenses and other current assets	(3,110)	(4,673)	(11,865)
Other assets	(1,190)	570	87
Accounts payable	3,899	1,952	691
CEPI accrual (Note 9)	-	-	(21,110)
Lease liabilities	(4,387)	(3,629)	(3,125)
Deferred revenue	-	-	(349,864)
Accrued and other liabilities	11,033	19,809	(24,788)
Net cash provided by operating activities	66,512	100,563	62,716
Investing activities			
Purchases of marketable securities	(524,063)	(636,921)	(632,306)
Proceeds from maturities and redemptions of marketable securities	512,380	486,097	322,450
Purchases of property and equipment, net	(6,352)	(4,104)	(7,139)
Proceeds from sale of assets, net of transaction costs	-	1,000	1,000
Net cash used in investing activities	(18,035)	(153,928)	(315,995)
Financing activities			
Payments for repurchase of common stock	(100,000)	-	-
Proceeds from warrants exercises	-	-	8,455
Proceeds from exercise of stock options and/or release of restricted stock awards, net	5,529	6,360	9,639
Proceeds from Employee Stock Purchase Plan	1,760	1,535	1,431
Payments for taxes related to net share settlement of RSUs	(9,306)	(6,509)	-
Net cash (used in) provided by financing activities	(102,017)	1,386	19,525
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(862)	324	(443)
Net decrease in cash and cash equivalents, and restricted cash	(54,402)	(51,655)	(234,197)
Cash and cash equivalents, and restricted cash at beginning of year	150,556	202,211	436,408
Cash and cash equivalents, and restricted cash at end of year	$ 96,154	$ 150,556	$ 202,211
Supplemental disclosure of cash flow information			
Cash paid during the year for income taxes	$ 4,585	$ 2,014	$ 2,208
Cash paid during the year for interest	$ 5,638	$ 5,638	$ 5,638
Reclassification of contract asset from other current assets to other assets	$ -	$ 71,307	$ -
Reclassification of CEPI accrual to CEPI accrual long-term	$ -	$ (60,337)	$ -
Advance Payments forgiven per CEPI-Bio E Assignment Agreement (Note 9)	$ -	$ (47,401)	$ -
Non-cash investing and financing activities:			
Purchases of property and equipment, not yet paid	$ 1,723	$ 299	$ 1,015
Right-of-use assets obtained in exchange for operating lease liabilities	$ 925	$ 1,332	$ 2,848

See accompanying notes.

1. Organization

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company") is a commercial stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. Our first marketed product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] is approved in the United States, the European Union and the United Kingdom for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany.

We are advancing a pipeline of differentiated product candidates that leverage our CpG 1018® adjuvant, the adjuvant used in HEPLISAV-B, to develop improved vaccines in indications with unmet medical needs. These programs include vaccine candidates under development for shingles and a plague vaccine candidate program in collaboration with, and fully funded by the U.S. Department of Defense ("DoD"), and additional vaccine programs in preclinical development.

Additionally. we manufacture and have supplied in the past CpG 1018 adjuvant, the adjuvant used in HEPLISAV-B, through both commercial supply agreements, and through preclinical and clinical research collaborations with third-party organizations. As of December 31, 2022, we had satisfied all delivery obligations under our commercial supply agreements.

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, Dynavax India LLP in India and a branch of Dynavax in Italy. All intercompany accounts and transactions among the entities have been eliminated from the consolidated financial statements.

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 may differ materially from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Foreign Currency Translation

We consider the local currency to be the functional currency for our international subsidiaries, Dynavax GmbH, located in Düsseldorf, Germany, Dynavax India LLP, and a branch of Dynavax registered in Italy. 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 (loss) income in stockholders' equity.

As of December 31, 2024 and 2023, the cumulative translation adjustments balances reflected losses of $5.3 million and $3.0 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, 2024, 2023 and 2022, we reported an unrealized foreign currency translation (loss) gain of $(2.4) million, $1.1 million and $(1.8) million, respectively. Realized gains and losses resulting from currency transactions are included in other (expense) income in the consolidated statements of operations. For the years ended December 31, 2024, 2023 and 2022, we reported a gain (loss) of $0.3 million, $(0.1) million and $0.1 million, respectively, resulting from currency transactions in our consolidated statements of operations.

Segment Information

Operating segments are defined as components of an entity for which discrete financial information is available that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. Our Chief Executive Officer is the CODM. The CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, management has determined that we operate in one operating segment that is focused on the discovery, development, and commercialization of innovative vaccines. Net assets outside of the U.S. were less than 10% of total net assets as of December 31, 2024 and 2023. See Note 11.

Cash and 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. Commencing with our adoption of Accounting Standards Codification ("ASC") 326, *Financial Instruments — Credit Losses ("ASC 326")* on January 1, 2023, we determine whether a decline in the fair value of our available-for-sale ("AFS") debt securities below their amortized cost basis (i.e., an impairment) is due to credit-related factors or noncredit-related factors. Any impairment that is not credit related is recognized in other comprehensive (loss) income, net of applicable taxes. Credit-related impairments (if any) are recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Both the allowance and the adjustment to net income can be reversed if conditions change. To date, there have been no declines in fair value that have been identified as a credit-related impairment.

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 significant 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. During the year ended December 31, 2023, we recorded an allowance for doubtful accounts of $12.3 million, which was determined by assessing changes in Biological E. Limited's ("Bio E") credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3 (See Note 9), and Bio E's dependence on cash collections from the Government of India, which have been delayed and significantly reduced in connection with the overall reduction in demand for CORBEVAX from the Government of India. As of December 31, 2024 and 2023, three customers collectively represented approximately 97% and 81% of our HEPLISAV-B 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 product candidates 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 that could affect our authorizations in the future.

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.

Our long-lived assets located in the United States as of December 31, 2024 and 2023, represented 26% and 31% of our total assets, respectively, and the remaining long-lived assets were located in Germany.

Inventories

HEPLISAV-B Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the years ended December 31, 2024 and 2023, there were no material inventory reserves or 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. Instead, those are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained.

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, while 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. Where 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. There have been no material adjustments to these estimates during the years presented.

Leases

We determine if an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset, and whether we have the right to control the identified asset. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities and long-term portion of lease liabilities in our consolidated balance sheets. ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments arising from the lease. The classification of our leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of ROU assets and lease liabilities is based on the present value of future lease payments over the lease term. The ROU asset also includes the effect of any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable.

As the implicit rate in our leases is generally unknown, we use our incremental borrowing rate based on information available at the lease commencement date in determining the present value of future lease payments. We consider our credit risk, term of the lease, total lease payments and adjust for the impacts of collateral, as necessary, when

calculating our incremental borrowing rate. The lease terms may include options to extend or terminate the lease when it is reasonably certain we will exercise any such options. Rent expense for our operating leases is recognized on a straight-line basis over the lease term. Variable lease payments are recorded as an expense in the period incurred.

We have elected not to apply the recognition requirements of ASC 842, *Leases ("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

Goodwill represents the excess purchase price over the fair value of tangible and intangible assets acquired and liabilities assumed. Our goodwill balance relates to our acquisition of Dynavax GmbH in 2006. Goodwill is not amortized, but instead is reviewed for impairment at least annually, or more frequently if events occur or circumstances change that would indicate the carrying amount may be impaired. Goodwill is assigned to, and impairment testing is performed at, the reporting unit level. 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. No impairment has been identified for the years presented.

Convertible Notes

We account for our 2.50% convertible senior notes due in 2026 (“Convertible Notes”), 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 (See Note 10). 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, *Derivatives and Hedging ("ASC 815")*. The capped calls purchased in connection with the Convertible Notes financing ("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 ASC 606, *Revenue from Contracts with Customers ("ASC 606")*, we apply the following five step model:

- identify the contract(s) with a customer;
- identify the performance obligation(s) in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligation(s) in the contract; and
- recognize revenue when (or as) we satisfy a performance obligation.

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 - HEPLISAV-B, 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.

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.

Other Revenue

Other revenue includes revenue from our agreement with the DoD, 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"), market-based performance stock units ("PSUs") 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, we use 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, we determine 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, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, we re-assesses the estimated performance and updates the number of performance-based awards that we believe will ultimately vest.

Fair value of RSUs is determined at the date of grant using our closing stock price, with the exception of PSUs, 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 expense recognized in future periods. We derive the expected term assumption primarily based on our historical settlement experience, while considering options that have not yet completed a full life cycle. Stock-based compensation expense 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 expense 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.

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 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.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. We adopted ASU 2023-07 in the fiscal year beginning January 1, 2024. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal

years beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires the disaggregation of certain expense captions into specified categories in disclosures within the notes to the financial statements to provide enhanced transparency into the expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or retrospectively to any or all prior periods presented in the financial statements. We are currently evaluating the impact of adopting ASU 2024-03.

In November 2024, the FASB issued ASU 2024-04, *Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, which amends ASC 470-202 and seeks to clarify the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU 2024-04 is effective for all entities for annual reporting periods beginning after 15 December 2025, and interim periods within those annual reporting periods. Early adoption is permitted for all entities that have adopted the amendments in ASU 2020-06. We are currently evaluating the impact of adopting ASU 2024-04.

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, 2024 and 2023.

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) measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2024				
Assets				
Money market funds	$ 83,726	$ -	$ -	$ 83,726
U.S. treasuries	-	199,879	-	199,879
U.S. government agency securities	-	158,871	-	158,871
Corporate debt securities	-	259,201	-	259,201
Total assets	$ 83,726	$ 617,951	$ -	$ 701,677

	Level 1	Level 2	Level 3	Total
December 31, 2023				
Assets				
Money market funds	$ 131,635	$ -	$ -	$ 131,635
U.S. treasuries	-	74,237	-	74,237
U.S. government agency securities	-	216,688	-	216,688
Corporate debt securities	-	308,552	-	308,552
Total assets	$ 131,635	$ 599,477	$ -	$ 731,112

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

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

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

The following table provides a reconciliation of cash and 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 (in thousands):

	December 31,		
	2024	2023	2022
Cash and cash equivalents	$ 95,883	$ 150,279	$ 202,004
Restricted cash [(1)]	271	277	207
Total cash and cash equivalents, and restricted cash shown in the consolidated statements of cash flows	$ 96,154	$ 150,556	$ 202,211

(1) Restricted cash is included in "Other assets" in the Consolidated Balance Sheets.

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2024				
Cash and cash equivalents:				
Cash	$ 12,157	$ -	$ -	$ 12,157
Money market funds	83,726	-	-	83,726
Total cash and cash equivalents	95,883	-	-	95,883
Marketable securities available-for-sale:				
U.S. treasuries	199,741	460	(322)	199,879
U.S. government agency securities	158,605	486	(220)	158,871
Corporate debt securities	259,004	418	(221)	259,201
Total marketable securities available-for-sale	617,350	1,364	(763)	617,951
Total cash and cash equivalents, and marketable securities	$ 713,233	$ 1,364	$ (763)	$ 713,834
December 31, 2023				
Cash and cash equivalents:				
Cash	$ 11,190	$ -	$ -	$ 11,190
Money market funds	131,635	-	-	131,635
Corporate debt securities	7,453	1	-	7,454
Total cash and cash equivalents	150,278	1	-	150,279
Marketable securities available-for-sale:				
U.S. treasuries	74,109	172	(44)	74,237
U.S. government agency securities	216,265	692	(269)	216,688
Corporate debt securities	300,803	315	(20)	301,098
Total marketable securities available-for-sale	591,177	1,179	(333)	592,023
Total cash and cash equivalents, and marketable securities	$ 741,455	$ 1,180	$ (333)	$ 742,302

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

	December 31, 2024	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 401,939	$ 402,738
Mature after one year through two years	215,411	215,213
	$ 617,350	$ 617,951

We have classified our entire investment portfolio as available-for-sale ("AFS") and available for use in current operations and accordingly have classified all investments as short-term. Our AFS 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. Unrealized losses are included in accumulated other comprehensive loss in stockholders' equity. We determine whether a decline in the fair value of our AFS debt securities below their amortized cost basis (i.e., an impairment) is due to credit-related factors or noncredit-related factors. Any impairment that is not credit related is recognized in other comprehensive (loss) income, net of applicable taxes. Credit-related impairments (if any) are recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Both the allowance and the adjustment to net income can be reversed if conditions change.

There were no realized gains or losses from the sale of marketable securities for the years ended December 31, 2024 and 2023. We do not intend to sell, and are not required to sell, the investments that are in an

unrealized loss position before recovery of their amortized cost basis. For the year ended December 31, 2024, we did not record an allowance for credit losses, as management believes any such losses would be immaterial based on the investment-grade credit rating for each of the investments as of December 31, 2024. As such, there have been no declines in fair value that have been identified as a credit-related impairment.

5. Inventories

The following table presents inventories (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 42,639	$ 27,256
Work-in-process	14,569	18,954
Finished goods	12,846	7,080
Total	$ 70,054	$ 53,290

6. Property and Equipment, net

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

	Estimated Useful Life (In years)	December 31,	
		2024	2023
Manufacturing equipment	5-13	$ 15,537	$ 15,752
Lab equipment	5-13	2,610	2,827
Computer equipment	3	5,913	5,060
Furniture and fixtures	3-13	2,450	2,467
Leasehold improvements	2-12	36,535	37,201
Assets in progress		10,122	5,822
		73,167	69,129
Less accumulated depreciation and amortization		(34,166)	(31,832)
Total		$ 39,001	$ 37,297

Depreciation and amortization expense on property and equipment was $4.6 million, $4.3 million and $3.8 million for the years ended December 31, 2024, 2023 and 2022, respectively.

7. Current Accrued Liabilities

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

	December 31,	
	2024	2023
Payroll and related expenses	$ 18,025	$ 17,069
Revenue reserve accruals	31,479	21,004
Accrued inventory	3,147	4,456
Other accrued liabilities	8,415	6,919
Total	$ 61,066	$ 49,448

8. Commitments and Contingencies

Leases

We lease our facilities in Emeryville, California and Düsseldorf, Germany. We lease and sublease certain manufacturing and office space with lease terms ranging from 3 to 12 years. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include options to renew or extend the lease for two successive five-year terms. These optional periods have not been considered in the determination of the right-of-use assets or lease liabilities associated with these leases as we did not consider the exercise of these options to be reasonably certain.

Sublease Termination and New Sublease

On February 22, 2024, our third-party subtenant obtained the approval of a voluntary petition for relief under Chapter 11 of the United States Code. As a consequence, the sublease agreement with that third-party for the subleased premises (approximately 75,662 square feet of office/laboratory space located at 5959 Horton Street, Emeryville, California) was terminated effective March 7, 2024. Simultaneously, on March 7, 2024, we entered into a new sublease agreement with a different third-party under similar conditions and for the same premises. Rent from the new sublease agreement is subject to scheduled annual increases, and the subtenant is responsible for certain operating expenses and taxes throughout the life of the sublease. The new sublease term expires on March 31, 2031, unless earlier terminated, concurrent with the term of our lease. The subtenant has no option to extend the sublease term.

As a result of the termination of the existing sublease agreement, we recognized a net loss of approximately $3.5 million during the year ended December 31, 2024, comprising primarily of a $4.8 million write-off of the accrued rent asset balance as of March 7, 2024, partially offset by the collection of a termination payment of $1.3 million.

We also sublease one of our leased premises to a third party. Rent is subject to scheduled annual increases and the subtenant is responsible for certain operating expenses and taxes throughout the life of the sublease. The sublease term expires on March 31, 2031, unless earlier terminated, concurrent with the term of our lease. The subtenant has no option to extend the sublease term. Sublease income was $5.0 million, $7.6 million and $7.7 million for the years ended December 31, 2024, 2023 and 2022, respectively. Both the net loss on sublease termination and the sublease income are included net in “Sublease income” within “Other income (expense)” in our consolidated statements of operations. Rent received from the subtenant in excess of rent paid to the landlord shall be shared by paying the landlord 50% of the excess rent. The excess rent is considered a variable lease payment and the total estimated payments are being recognized as additional rent expense on a straight-line basis.

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

	Year Ended December 31,		
	2024	2023	2022
Operating lease expense	$ 5,702	$ 5,563	$ 6,222

Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2024, 2023, and 2022 was $7.6 million, $7.2 million, and $6.8 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,	
	2024	2023
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 4,175	$ 4,496
Long-term portion of lease liabilities	26,388	29,720
Total operating lease liabilities	$ 30,563	$ 34,216

As of December 31, 2024, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2025	$ 6,127	$ 6,941
2026	6,342	6,514
2027	6,564	6,458
2028	6,794	6,443
2029	7,031	6,346
Thereafter	9,160	8,605
Total	$ 42,018	41,307
Less:		
Present value adjustment		(10,744)
Total		$ 30,563

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

	December 31,	
	2024	2023
Weighted average remaining lease term	5.9 years	6.7 years
Weighted average discount rate	10.1%	10.1%

Commitments

As of December 31, 2024, our material non-cancelable purchase and other commitments for the supply of HEPLISAV-B totaled $80.5 million. The following summarizes our material purchase commitments at December 31, 2024 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)
2025	$ 25,148
2026	16,265
2027	16,265
2028	11,212
2029	11,660
Thereafter	-
Total	$ 80,550

The amounts presented in the table above include obligations under a contract that was executed subsequent to December 31, 2024. These obligations have been included to provide a comprehensive view of our future commitments as of the filing date of this report.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B. In November 2013, we entered into a Commercial Manufacturing and Supply Agreement with Baxter Pharmaceutical Solutions LLC ("Baxter") that was amended in September 2021 and January 2025 (as amended, the "Baxter Agreement"). Baxter provides formulation, fill and finish services and produces HEPLISAV-B for commercial use. Pursuant to the Baxter Agreement, we are obligated to purchase an annual minimum number of batches of HEPLISAV-B through December 31, 2029, and there are certain limits on the number of batches that Baxter is required to produce. As of December 31, 2024, our aggregate minimum commitment under the Baxter Agreement was $17.0 million within the next 12 months, and $55.4 million beyond the next 12 months.

On September 7, 2023 (the "Effective Date"), we entered into an agreement (the "Avecia Supply Agreement") with Nitto Denko Avecia Inc. ("Avecia") for the manufacture and supply of our CpG 1018 adjuvant using a specific production process. Under the Avecia Supply Agreement, Avecia has agreed to produce and supply to us quantities

of CpG 1018 adjuvant ordered by us after the Effective Date. Subject to certain conditions in the Avecia Supply Agreement, we are obligated to purchase all of our annual volume requirements of CpG 1018 adjuvant from Avecia up to a specified production capacity. We may alternatively order CpG 1018 adjuvant produced using a different production process pursuant to the existing supply agreement between us and Avecia dated October 1, 2012 (the "2012 Agreement"). As of December 31, 2024, our aggregate minimum commitment for the supply of CpG 1018 adjuvant under the Avecia Supply Agreement was $8.2 million within the next 12 months.

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, 2024, the aggregate principal amount of our convertible senior notes ("Convertible Notes") was $225.5 million, excluding debt discount of $1.6 million (See Note 10).

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, 2024 and was 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, 2024 and 2023.

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 our immune-oncology compound, SD-101. In July 2020, we sold assets related to SD-101 to Surefire Medical, Inc. d/b/a TriSalus Life Sciences ("TriSalus"). We paid $2.5 million to Holdings in August 2020. In each of September 2021, May 2022 and September 2023, we received $1.0 million from TriSalus because it met pre-commercialization milestones. We recorded the proceeds as gain on sale of assets in our consolidated statements of operations. We paid Holdings $0.5 million in each of September 2021, May 2022 and October 2023. We included the payments in selling, general and administrative expenses in our consolidated statements of operations.

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, results of operations, or cash flows in a particular period.

9. Collaborative Research, Development and License Agreements

Coalition for Epidemic Preparedness Innovations

In January 2021, we entered into an agreement (together with subsequent amendments, the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant ("CpG 1018 Materials"). In May 2021, we entered into the first amendment to the CEPI Agreement. The CEPI Agreement enables CEPI to direct the supply of CpG 1018 Materials to CEPI partner(s). CEPI partner(s) would purchase CpG 1018 Materials under separately negotiated agreements. 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"). 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.

On April 27, 2023, we entered into a waiver and second amendment to the CEPI Agreement by and between us and CEPI (the "CEPI-Bio E Assignment Agreement"). Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of the outstanding Advance Payments for CpG 1018 Materials allocated to and ordered by Bio E under the CEPI Agreement and has assumed our previous rights to $47.4 million of Bio E accounts receivable.

Through December 31, 2024, we received Advance Payments totaling approximately $175.0 million pursuant to the CEPI Agreement, of which $67.3 million have been repaid and $47.4 million have been forgiven (as discussed above). As of December 31, 2024, remaining Advance Payments totaling $60.3 million in CEPI accrual long-term were reflected in our consolidated balance sheets, representing the outstanding balance of the Advance Payments relating to the Clover Supply Agreement (as defined and discussed below). There were no deferred revenue balances related to the CEPI Agreement as of December 31, 2024 and December 31, 2023.

Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with Clover's COVID-19 vaccine candidate, SCB-2019 (together with subsequent amendments, the "Clover Supply Agreement"). Under the Clover Supply Agreement, Clover 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. In 2022 and 2023, we signed four amendments to the Clover Supply Agreement. The terms and conditions of the Clover Supply Agreement were operative through December 31, 2022, and as of December 31, 2022, we had satisfied all delivery obligations thereunder.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay us 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. 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.

The contract asset of $71.3 million relating to Clover was included in other current assets as of December 31, 2024 and December 31, 2023. The contract asset was included in other assets (long term) to reflect the timing of expected long term demand for CpG 1018 adjuvant for Clover Product.

Corresponding Advance Payments of $60.3 million relating to Clover are recorded in CEPI accrual long-term in our consolidated balance sheets as of December 31, 2024. These Advance Payments may be repaid using cash collected from Clover or forgiven in accordance with the CEPI Agreement. We had no accounts receivable balance from Clover as of December 31, 2024 and December 31, 2023.

Biological E. Limited

In July 2021, we entered into an agreement (together with subsequent amendments, 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 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. In June 2022 and in October 2022, we entered into amendments to the Bio E Supply Agreement (the "Bio E Amendment No. 1" and the "Bio E Amendment No. 2," together the "Bio E Amendments"). The Bio E Amendments primarily established: (i) a new payment schedule for certain outstanding invoices related to the CEPI product to be the earlier of December 31, 2022, or receipt of certain amounts from Bio E from the Government of India in connection with their advance purchase agreement for CORBEVAX, and (ii) further modified the scope of the Bio E Supply Agreement, by reducing certain quantities of CpG 1018 adjuvant to be delivered. The terms and

conditions of the Bio E Supply Agreement were operative through December 31, 2022, and as of December 31, 2022, we had satisfied all delivery obligations thereunder.

As of December 31, 2024, we had no accounts receivable balance from Bio E. In 2023, we recorded an allowance for doubtful accounts of $12.3 million, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3 (defined below), and Bio E's dependence on cash collections from the Government of India, which have been delayed and significantly reduced in connection with the overall reduction in demand for CORBEVAX from the Government of India.

On April 26, 2023, we entered into a third amendment to the Bio E Supply Agreement (the "Bio E Amendment No. 3"), and on April 27, 2023, we entered into the CEPI-Bio E Assignment Agreement. Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to a liability for Advance Payments of $47.4 million (the "Bio E CEPI Advance Payments") for CpG 1018 Materials allocated to Bio E, and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Pursuant to the Bio E Amendment No. 3, we collected $14.5 million from Bio E (including $13.5 million in April 2023 and $1.0 million in August 2023). Accordingly, as of December 31, 2024, the CEPI-Bio E Assignment Agreement resulted in: (i) no accounts receivable balance, and (ii) the derecognition of $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

U.S. Department of Defense

In September 2021, we entered into an agreement with the DoD for the development of a recombinant plague vaccine adjuvanted with CpG 1018 adjuvant for approximately $22.0 million over two and a half years. Under the agreement, we are conducting a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. In July 2023, we executed a contract modification with the DoD to support advancement into a nonhuman primate challenge study, with the agreement now totaling $33.7 million through 2025. In December 2024, we executed a contract totaling $30.0 million to support additional Phase 2 clinical and manufacturing activities to be performed through the first half of 2027.

For the years ended December 31, 2024 and 2023, we recognized revenue of $8.6 million and $17.6 million, respectively, from the DoD agreement, which is included in other revenue in our consolidated statements of operations.

10. Convertible Notes

In May 2021, we issued $225.5 million of Convertible Notes in a private placement. 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 retire our previous loan agreement with CRG Servicing LLC and $27.2 million of the net proceeds to pay the costs of the Capped Calls described below.

The Convertible Notes are general, unsecured obligations and accrue interest at a rate of 2.5% 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 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:

- During any calendar quarter (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;
- During the five business day period after any ten consecutive trading day period (the "measurement period"), in which the "trading price" (as defined in 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;

- 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
- 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.

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, 2024.

We may redeem for cash all or any portion of the Convertible Notes (subject to the partial redemption limitation described in the indenture governing 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, but excluding, 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.

We accounted for the Convertible Notes as a single liability in accordance with ASU 2020-06 - *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). As of December 31, 2024, the Convertible Notes were recorded at the aggregate principal amount of $225.5 million less unamortized issuance costs of $1.6 million as a long-term liability on the consolidated balance sheets. As of December 31, 2024, the fair value of the Convertible Notes was $295.5 million. The fair value was estimated using a reputable third-party valuation model based on observable inputs and is considered Level 2 in the fair value hierarchy. 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,	
	2024	2023
Stated coupon interest	$ 5,636	$ 5,636
Amortization of debt issuance cost	1,158	1,121
Total interest expense	$ 6,794	$ 6,757

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. Segment Reporting

We operate in one operating segment that is focused on the discovery, development, and commercialization of innovative vaccines. The following table presents segment revenue, measures of our segment's profit or loss, and significant segment expenses:

	Year Ended December 31,		
	2024	2023	2022
Total revenues	$ 277,246	$ 232,284	$ 722,683
Less (add) [1]:			
Cost of sales - product	49,445	50,167	262,153
Research and development	61,550	54,886	46,600
Selling and marketing	98,170	86,727	79,125
General and administrative	72,203	66,219	52,283
Other segment items [2]	(31,431)	(19,326)	(10,634)
Segment net income (loss) [3]	$ 27,309	$ (6,389)	$ 293,156

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.
(2) Other segment items includes the net of: interest income, interest expense, sublease income, other expenses, provision for income taxes, gain on sale of assets and bad debt expense, as presented on the face of our consolidated statements of operations.
(3) Net income (loss) is our reported measure of segment profit or loss.

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, 2024			Year Ended December 31, 2023			Year Ended December 31, 2022		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net									
HEPLISAV-B	$ 264,973	$ 3,457	$268,430	$213,295	$ -	$213,295	$124,996	$ 941	$125,937
CpG 1018 adjuvant	-	-	-	-	-	-	-	587,708	587,708
Total product revenue, net	$ 264,973	$ 3,457	$268,430	$213,295	$ -	$213,295	$124,996	$588,649	$713,645
Other revenue	8,642	174	8,816	17,650	1,339	18,989	8,774	264	9,038
Total revenues	$ 273,615	$ 3,631	$277,246	$230,945	$ 1,339	$232,284	$133,770	$588,913	$722,683

Revenues from Major Customers and Collaboration Partners

All of our HEPLISAV-B sales in the U.S. are to certain wholesalers and specialty distributors whose principal customers include independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Department of Defense, the Department of Veterans Affairs and retail pharmacies. All of our HEPLISAV-B sales in Germany are to one distributor.

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

	Year Ended December 31,		
	2024	2023	2022
Largest customer	30%	28%	21%
Second largest customer	21%	27%	17%
Third largest customer	19%	17%	16%

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	Adjustments related to prior periods	Balance at End of Period
Year ended December 31, 2024:					
Accounts receivable reserves [1]	$ 7,011	$ 74,147	$ (71,831)	$ (10)	$ 9,317
Revenue reserve accruals [2]	$ 21,004	$ 55,052	$ (43,310)	$ (1,267)	$ 31,479
Year ended December 31, 2023:					
Accounts receivable reserves [1]	$ 8,179	$ 55,604	$ (54,143)	$ (2,629)	$ 7,011
Revenue reserve accruals [2]	$ 10,552	$ 46,062	$ (38,207)	$ 2,597	$ 21,004

(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 and perform services under our agreement with the DoD, 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	Subtractions	Reclassification [2]	Balance at End of Period
Year ended December 31, 2024:					
Contract asset, included in other current assets [1]	$ 1,389	$ 8,642	$ (9,680)	$ -	$ 351
Contract asset, included in other assets (long term)	$ 71,307	$ -	$ -	$ -	$ 71,307
Year ended December 31, 2023:					
Contract asset, included in other current assets	$ 71,965	$ 17,650	$ (16,919)	$ (71,307)	$ 1,389
Contract asset, included in other assets (long term)	$ -	$ -	$ -	$ 71,307	$ 71,307

(1) The $0.4 million of contract asset is derived from our agreement with the DoD.
(2) The Clover contract asset was reclassified to long term assets to reflect the timing of expected long term demand for CpG 1018 adjuvant for Clover Product. See Note 9 for further discussion.

13. Net Income (Loss) Per Share

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 per share, net income attributable to common stockholders for basic net income 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 per share attributable to common stockholders is computed by dividing the resulting net income attributable to common stockholders by the weighted-average number of fully diluted common shares outstanding.

The numerators and denominators of the basic net income (loss) and diluted net income per share computations for our common stock are calculated as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Numerator			
Net income (loss)	$ 27,309	$ (6,389)	$ 293,156
Less: undistributed earnings allocated to participating securities			(283)
Net income (loss) allocable to common stockholders, basic	27,309	(6,389)	292,873
Add: undistributed earnings allocated to Series B and warrants	-	-	283
Less: undistributed earnings allocated to Series B and warrants	-	-	-
Add: interest expense on convertible notes	-	-	5,044
Less: removal of change in fair value of warrant liability	-	-	(1,801)
Net income (loss) allocable to common stockholders, diluted	$ 27,309	$ (6,389)	$ 296,399
Denominator			
Weighted average shares used to compute net income (loss) allocable to common stockholders per share, basic	130,047	128,733	126,398
Effect of dilutive shares:			
Stock-based compensation plans	3,297	-	2,774
Convertible Notes (as converted to common stock)	-	-	21,543
Effect of dilutive warrants	-	-	82
Weighted average shares used to compute net income (loss) allocable to common stockholders per share, diluted	133,344	128,733	150,797
Net income (loss) per share attributable to common stockholders			
Basic	$ 0.21	$ (0.05)	$ 2.32
Diluted	$ 0.20	$ (0.05)	$ 1.97

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 (in thousands).

	December 31,		
	2024	2023	2022
Outstanding securities not included in diluted net income (loss) allocable to common stockholders per share calculation (in thousands):			
Stock options and stock awards	8,082	15,158	7,165
Convertible Notes (as converted to common stock)	21,543	21,543	-

14. Stockholder's Equity

Common Stock Outstanding

As of December 31, 2024, there were 125,449,558 shares of our common stock outstanding.

We entered into an at-the-market Sales Agreement with Cowen and Company, LLC (“Cowen”) on August 6, 2020 and an amendment to such agreement on August 3, 2023 (the sales agreement as amended, the “ATM

Agreement"). Under the ATM Agreement, 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 $120.0 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 ATM Agreement. As of December 31, 2024, we had approximately $120.0 million remaining under the ATM Agreement.

Share Repurchase Program

In November 2024, our Board of Directors authorized a share repurchase program (the "Program") allowing us to repurchase up to $200.0 million of our common stock. On November 8, 2024, we entered into an accelerated share repurchase agreement (the "ASR Agreement") with Goldman Sachs & Co. LLC ("Goldman") to repurchase an aggregate amount of $100.0 million of our common stock. Under the ASR agreement, we made an aggregate upfront payment of $100.0 million to Goldman and received an aggregate initial delivery of 6,149,116 shares of our common stock on November 12, 2024, representing approximately 80% of the total shares that would be repurchased under the ASR Agreement measured based on the closing price of our common stock on November 8, 2024.

The final number of shares that we ultimately repurchased pursuant to the ASR Agreement will be based on the average of the daily volume-weighted average ("VWAP") price per share of our common stock during the repurchase period, subject to adjustments pursuant to the terms and conditions of the ASR Agreement. The accelerated share repurchase terminated in February 2025. As of December 31, 2024, $100.0 million remained available for future repurchases under the Program.

Shares of our common stock repurchased under the ASR Agreement are immediately retired upon receipt and returned to authorized and unissued status. Repurchased common stock is reflected as a reduction of stockholders' equity. Any excess of cost over par value is charged to additional paid-in capital to the extent that a balance is present. Once additional paid-in capital is fully depleted, any remaining excess of cost over par value is charged to accumulated deficit.

Warrants

During the year ended December 31, 2022, all of the 1,882,600 outstanding warrants as of December 31, 2021 were exercised or expired, resulting in cash proceeds totaling $8.5 million. For the year ended December 31, 2022, we recognized the decrease in the estimated fair value of warrant liability of $1.8 million 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 our employees or directors. 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. The Amended 2021 Inducement Plan was terminated effective as of April 3, 2022 and, therefore, there are no shares of our common stock available for grant.

In May 2024, our stockholders approved the amendment and restatement of our 2018 Equity Incentive Plan (the "Amended 2018 EIP") to, among other things, increase the authorized number of shares of common stock by 11,400,000. The maximum number of shares of common stock that may be issued under the Amended 2018 EIP, will not exceed 41,440,250 shares of common stock. As of December 31, 2024, the Amended 2018 EIP and the Amended and Restated 2014 Employee Stock Purchase Plan are our active plans (the "Plans").

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, 2024, there were 14,122,413 shares of common stock reserved for issuance under the Amended 2018 EIP.

Under our Amended 2018 EIP, we may grant stock options, RSUs, performance-based awards, and other awards that are settled in shares of our common stock. Our equity awards generally vest over a three-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). Activity under our stock plans is set forth below:

Stock Options

The following table summarizes the activity of stock options for the year ended December 31, 2024:

	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, 2023	10,120	$ 10.78	4.18	$ 37,388
Options granted	1,974	12.40		
Options exercised	(706)	8.18		
Options cancelled:				
Options forfeited (unvested)	(70)	11.62		
Options expired (vested)	(176)	15.51		
Balance at December 31, 2024	11,142	$ 11.15	3.79	$ 24,210
Vested and expected to vest at December 31, 2024	11,004	$ 11.14	3.76	$ 24,144
Exercisable at December 31, 2024	8,408	$ 10.84	3.11	$ 22,323

Stock-based compensation expense related to options was approximately $17.1 million, $18.7 million, and $17.2 million for the years ended December 31, 2024, 2023 and 2022, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2024, 2023 and 2022 was $2.9 million, $5.0 million, and $7.7 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of our common stock as of the close of the exercise date.

The total fair value of stock options vested during the years ended December 31, 2024, 2023 and 2022 was $17.5 million, $19.5 million and $17.5 million, respectively.

Restricted Stock Units

The following table summarizes the activity of RSUs for the year ended December 31, 2024:

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2023	4,445	$ 11.57
Granted	3,296	12.43
Vested [(1)]	(1,940)	11.28
Forfeited	(438)	12.21
Non-vested as of December 31, 2024	5,363	$ 12.15

(1) Inclusive of approximately 740,339 RSUs for the year ended December 31, 2024, which were not converted into shares due to net share settlement in order to cover the required amount of employee withholding taxes. The value of the withheld shares was classified as a reduction to additional paid-in capital.

Stock-based compensation expense related to RSUs was approximately $28.7 million, $20.4 million, and $13.2 million for the years ended December 31, 2024, 2023, and 2022, respectively. The aggregate fair value of the RSUs outstanding as of December 31, 2024, 2023, and 2022, based on our stock price on that date, was $68.5 million, $62.2 million, and $37.0 million, respectively.

The total fair value of RSUs vested during the years ended December 31, 2024, 2023, and 2022 was $24.3 million, $16.1 million, and $15.7 million, respectively.

Market-based Performance Stock Units

We granted PSUs to certain executives. These PSUs vest upon a specified market condition. The summary of PSU activities for the year ended December 31, 2024 is as follows:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2023	557	$ 15.95
Granted	558	17.23
Non-vested as of December 31, 2024	1,115	$ 16.59

Stock-based compensation expense related to PSUs was approximately $5.7 million, $2.5 million, and $0.8 million for the years ended December 31, 2024, 2023, and 2022, respectively. The aggregate intrinsic value of the PSUs outstanding as of December 31, 2024, 2023 and 2022, based on our stock price on that date, was $14.2 million, $7.8 million, and $2.1 million, respectively.

Performance-based Options

As of December 31, 2024, approximately 36,000 shares underlying performance-based options were outstanding.

Significant Assumptions in Estimating Option Fair Value

The fair value of each time-based 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 Year Ended December 31,			Market-Based Performance Stock Units Year Ended December 31,			Employee Stock Purchase Plan Year Ended December 31,		
	2024	2023	2022	2024	2023	2022	2024	2023	2022
Weighted-average fair value	$ 7.75	$ 7.32	$ 7.95	$ 17.23	$ 18.25	$ 11.62	$ 4.21	$ 5.35	$ 7.37
Risk-free interest rate	4.2%	4.0%	2.0%	4.3%	4.3%	1.7%	4.7%	4.9%	2.1%
Expected life (in years)	4.5	4.5	4.5	2.9	2.9	2.9	1.2	1.3	1.3
Expected volatility	0.8	0.8	0.8	0.6	0.9	0.9	0.4	0.7	1.0

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

Stock-based Compensation

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.

We have 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.

The following table summarizes stock-based compensation expense recorded in each component of operating expenses in our consolidated statements of operations, and amounts capitalized to our inventories (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Employees and directors stock-based compensation expense	$ 52,619	$ 42,592	$ 32,915

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 11,849	$ 9,285	$ 5,954
Selling, general and administrative	35,405	29,069	23,118
Cost of sales - product	1,963	1,839	1,123
Inventories	3,402	2,399	2,720
Total	$ 52,619	$ 42,592	$ 32,915

As of December 31, 2024, the total unrecognized compensation cost related to non-vested stock options and RSUs deemed probable of vesting, including all stock options with time-based vesting, net of estimated forfeitures, amounted to $50.0 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years. As of December 31, 2024, the total unrecognized compensation cost related to PSUs amounted to $9.2 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, 2024, employees have acquired approximately 184,000 shares of our common stock under the Employee Stock Purchase Plan and approximately 538,000 shares of our common stock remained available for future purchases under the Employee Stock Purchase Plan.

As of December 31, 2024, the total unrecognized compensation cost related to shares of our common stock under the Employee Stock Purchase Plan amounted to $0.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years.

16. Employee Benefit Plan

We maintain a 401(k) Plan, which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. We may, at our discretion, contribute for the benefit of eligible employees. Our contribution to the 401(k) Plan was approximately $1.8 million, $1.3 million and $0.9 million for the years ended December 31, 2024, 2023 and 2022, respectively.

17. Income Taxes

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

	Year Ended December 31,		
	2024	2023	2022
U.S.	$ 28,083	$ (6,275)	$ 292,460
Non U.S.	2,772	1,908	1,839
Total	$ 30,855	$ (4,367)	$ 294,299

The components of the consolidated income tax provision for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Current			
Federal	$ 794	$ (178)	$ (165)
State	1,828	1,533	897
Non-US	924	667	411
Total current tax expense	3,546	2,022	1,143
Deferred			
Federal	-	-	-
State	-	-	-
Non-US	-	-	-
Total deferred tax expense	-	-	-
Total income tax expense	$ 3,546	$ 2,022	$ 1,143

The difference between the consolidated income tax provision and the amount computed by applying the federal statutory income tax rate to the consolidated income before income taxes in the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Income tax provision (benefit) at federal statutory rate	$ 6,480	$ (917)	$ 61,775
State tax	1,513	574	(2,942)
Business credits	(623)	(2,050)	(3,246)
Uncertain tax positions	156	334	586
Deferred compensation charges	2,410	830	(473)
Change in valuation allowance	(7,862)	1,466	(324)
Section 162(m) limitation	1,986	1,963	1,779
Mark-to-market of warrants	-	-	(378)
Net operating loss and tax credit limitation	(329)	-	(56,908)
Other [1]	(144)	(518)	879
Foreign taxes	(41)	340	395
Total income tax expense	$ 3,546	$ 2,022	$ 1,143

(1) Certain prior year amounts have been reclassified to conform to the current year presentation. In 2022, Foreign taxes were included in Other.

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

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 77,843	$ 96,336
Research credit carryforwards	32,516	34,940
Section 174 capitalization	28,446	22,556
Lease liability	6,914	8,868
Stock compensation	11,479	10,572
Accruals and reserves	21,579	15,808
Other	563	348
Total deferred tax assets	179,340	189,428
Less valuation allowance	(172,525)	(180,387)
Net deferred tax assets	6,815	9,041
Deferred tax liabilities:		
Fixed assets	(2,101)	(2,667)
Operating lease right-of-use assets	(4,714)	(6,345)
Other	—	(29)
Total deferred tax liabilities	(6,815)	(9,041)
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 as of December 31, 2024, 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.

The valuation allowance decreased by $7.9 million during the year ended December 31, 2024 and increased by $1.5 million during the year ended December 31, 2023. The increase in valuation allowance during the year ended December 31, 2024 was due to a decrease in our deferred tax assets, predominantly related to utilization of net operating losses and research and development credits offset by Section 174 capitalization and increased reserves. The increase in valuation allowance during the year ended December 31, 2023 was due to an increase in our deferred tax assets, predominantly related to Section 174 capitalization and increased reserves offset largely by utilization of net operating losses.

As of December 31, 2024, we had federal net operating loss carryforwards of approximately $0.4 million, which began to expire in the year 2025, federal net operating loss carryforwards of approximately $293.1 million, which do not expire and federal research and development tax credits of approximately $26.5 million, which expire in the years 2025 through 2044.

As of December 31, 2024, we had net operating loss carryforwards for California and other states for income tax purposes of approximately $262.9 million, which expire in the years 2025 through 2041, and California state research and development tax credits of approximately $21.8 million, which do not expire.

As of December 31, 2024, we had no remaining net operating loss carryforwards for foreign income tax purposes.

Uncertain Income Tax positions

The total amount of unrecognized tax benefits was $12.4 million and $12.1 million as of December 31, 2024 and 2023, 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:

	Year Ended December 31,	
	2024	2023
Balance at beginning of year	$ (12,101)	$ (11,339)
Tax positions related to the current year		
Additions	(569)	(762)
Reductions	-	-
Tax positions related to the prior year		
Additions	270	-
Reductions	-	-
Settlements	-	-
Lapses in statute	-	-
Balance at end of year	$ (12,400)	$ (12,101)

Our policy is to account for interest and penalties as income tax expense. As of December 31, 2024, there were no interest and no material penalties recognized in the provision for income taxes. As of December 31, 2023, there were no interest and no penalties 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. For the year ended December 31, 2021, we completed a preliminary analysis under Section 382 of the Internal Revenue Code indicating we experienced ownership changes in 2008, 2010, 2012, and 2019 that limited the future use of our pre-change federal and state net operating loss carryforwards and federal research and development tax credits. We finalized the study during the year ended December 31, 2022 and concluded that we only experienced ownership changes in 2008, 2010, and 2012, resulting in a significant reduction in the federal and state net operating loss carryforwards and federal research and development tax credits that are expected to expire unused. We have revised the net operating loss carryforwards and research and development tax credits that are expected to expire unused as a result of the annual limitations in the deferred tax assets and corresponding uncertain tax positions as of December 31, 2022. There were no changes to our Section 382 analysis as of December 31, 2024.

We are subject to income tax examinations for U.S. federal and state income taxes from 2001 forward. We are subject to tax examination in Germany from 2020 forward, in India from 2021 forward and in Italy from 2021 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 Principal 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 Principal Executive Officer and our Principal 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, 2024. Our 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 our 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, 2024, 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, 2024, 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, 2024 and 2023, 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, 2024 and the related notes and our report dated February 20, 2025 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 20, 2025

(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

Trading Arrangements

During our last fiscal quarter, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of our securities set forth in the table below.

			Type of Trading Arrangement				
Name and Position	**Action**	**Adoption/ Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Common Stock to be Sold**	**Total Shares of Common Stock to be Purchased**	**Expiration Date**
David Novack, *President and Chief Operating Officer*	Adoption	December 6, 2024	X		684,000 shares of common stock underlying stock options; up to 47,977 shares of common stock underlying restricted stock units; and up to 26,500 shares of common stock underlying performance-based restricted stock units		February 20, 2026, unless earlier terminated (i) by Mr. Novack or (ii) on the first date on which all trades under Mr. Novack's plan have been executed or are expired
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.							
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.							

Resolution of Class Action Law Suit

As previously disclosed, on October 28, 2024, our Board of Directors (the "Board") adopted a limited-duration stockholder rights plan (the "Rights Agreement").

On November 26, 2024, plaintiff Terry Ignasiak (the "Plaintiff") filed a putative class action complaint (the "Complaint") in the Court of Chancery of the State of Delaware (the "Court") against the Company and the Board under the caption Ignasiak v. Dynavax Technologies Corporation et al., C.A. No. 2023-1219-JTL (the "Action"). The Action alleged, among other things, that Section 28 of the Rights Agreement improperly eliminated all liability of the Board for any action conducted in connection with the Rights Agreement.

After the Complaint was filed, on December 26, 2024, we entered into Amendment No. 1 (the "Amendment") to the Rights Agreement. The Amendment removed and replaced Section 28 of the Rights Agreement making certain technical amendments to the rights and obligations of the Board to administer and make determinations with respect to the Rights Agreement and the rights issued thereunder. In particular, the Amendment confirms that nothing in the Rights Agreement, express or implied, including any provision requiring or permitting the Board to take (or refrain from taking) any action or making any determination shall be deemed to limit or eliminate the fiduciary duties of the Board under applicable law. The Rights Agreement otherwise remains unmodified and in full force and effect in accordance with its terms.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the complete text of the Amendment, a copy of which we filed with the U.S. Securities and Exchange Commission (the "SEC") on December 27, 2024 as Exhibit 4.1 to a Current Report on Form 8-K.

The Company denies and continues to deny all allegations of wrongdoing in the Action. We and the Plaintiff agreed that the Amendment and our actions related to the Amendment rendered Plaintiff's claims moot. We also subsequently agreed to pay $155,000 in attorneys' fees and reimbursement of expenses (the "Mootness Fee," inclusive of a

$500 service award to Plaintiff) in full satisfaction of any and all claims by Plaintiff and his counsel for fees and expenses in the Action. The Court has not and will not pass judgment on the amount of the Mootness Fee.

On February 17, 2025, the Court entered an order closing the Action, subject to us filing an affidavit with the Court confirming that these disclosures in this Annual Report on Form 10-K, which shall constitute notice to the putative class for purposes of Delaware Court of Chancery Rule 23, have been filed with the SEC.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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—Election of Directors," "Executive Officers," "Corporate Governance" and "Delinquent Section 16(a) Reports" in our Definitive Proxy Statement in connection with the 2025 Annual Meeting of Stockholders (the "Proxy Statement") which we expect will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2024.

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 header "Investors" and within that under the header "Corporate Governance and Compliance" 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 720, Emeryville, CA 94608, (510) 848-5100.

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K. In addition, it is our practice to comply with the applicable laws and regulations relating to insider trading.

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 sections 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 Plan Information" 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" 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 Certificate of Designation of Series A Junior Participating Preferred Stock filed with the Secretary of State of the State of Delaware on October 29, 2024	3.1	8-K	October 29, 2024	001-34207	
3.10	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	

4.1	Description of Capital Stock					X
4.2	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10 above					
4.3	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.4	Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021	4.1	8-K	May 13, 2021	001-34207	
4.5	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	
4.6	Rights Agreement, dated as of October 28, 2024, between Company and Computershare Trust Company, N.A., which includes the form of Amended and Restated Certificate of Designation as Exhibit A and the form of Right Certificate as Exhibit B	4.1	8-K	October 29, 2024	001-34207	
4.7	Amendment No. 1, dated as of December 26, 2024, to Rights Agreement, dated as of October 28, 2024, by and between Company and Computershare Trust Company, N.A., as Rights Agent	4.1	8-K	December 27, 2024	001-34207	
10.1+	Employment Agreement, dated July 12, 2013, by and between Robert Janssen, M.D. and Company	10.85	10-K	March 10, 2014	001-34207	
10.2+	Chief Executive Officer Letter, dated December 13, 2019, between Company and Ryan Spencer	10.17	10-K	March 11, 2020	001-34207	
10.3+	President and Chief Operating Officer Letter, dated December 13, 2019, between Company and David Novack	10.18	10-K	March 11, 2020	001-34207	
10.4+	Offer Letter, dated December 14, 2020, by and between Company and Kelly MacDonald	10.33	10-K	February 25, 2021	001-34207	
10.5+	Offer Letter, dated May 26, 2021, by and between Company and John Slebir					X
10.6+	Consulting Agreement, effective January 16, 2023, between Company and Peter Paradiso	10.1	10-Q	May 2, 2023	001-34207	

10.7+	Amendment No. 1 to Consulting Agreement and Statement of Work No. 1, effective January 16, 2025, between Company and Peter Paradiso					X
10.8+	Form of Indemnification Agreement	10.1	10-Q	November 7, 2019	001-34207	
10.9+	Form of Management Continuity and Severance Agreement between Company and certain of its executive officers	10.3	10-Q	August 3, 2023	001-34207	
10.10+	Dynavax Technologies Corporation Annual Bonus Plan	10.2	10-Q	August 6, 2024	001-34207	
10.11+	Non-Employee Director Compensation Policy					X
10.12	Sales Agreement, dated August 6, 2020, between Company and Cowen and Company, LLC	10.3	10-Q	August 6, 2020	001-34207	
10.13	Amendment No. 1 to Sales Agreement with Cowen and Company, LLC	1.3	S-3 ASR	August 3, 2023	333-273674	
10.14	Form of Confirmation for Capped Call Transactions	10.1	8-K	May 13, 2021	001-34207	
10.15+	Dynavax Technologies Corporation Amended and Restated 2014 Employee Stock Purchase Plan	Appendix A	DEF 14A	April 16, 2021	001-34207	
10.16+	Dynavax Technologies Corporation 2018 Equity Incentive Plan	10.1	10-Q	August 6, 2024	001-34207	
10.17+	Form of Option Grant Notice and Option Agreement under the 2018 Equity Incentive Plan	10.3	8-K	June 1, 2018	001-34207	
10.18+	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	
10.19+	Restricted Stock Unit Award Agreement for Directors under the 2018 Equity Incentive Plan	10.11	10-K	February 28, 2022	001-34207	
10.20+	Amended and Restated Dynavax Technologies Corporation 2021 Inducement Award Plan	10.3	10-Q	August 4, 2021	001-34207	
10.21•	Office/Laboratory Lease, dated September 17, 2018, between Company and Emery Station West, LLC	10.1	10-Q	November 6, 2018	001-34207	
10.22•	Sublease, dated March 7, 2024, by and between Company and Metagenomi, Inc.	10.1	10-Q	May 8, 2024	001-34207	

10.23•	English Translation of 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	
10.24•	English Translation of Addendum to Commercial Lease Agreement, dated January 4, 2024, by and between Onyx Düsseldorf S.à r.l. and Dynavax GmbH					X
10.25•	Lease Agreement, dated March 15, 2022, by and between Company and SPUS8 2100 Powell, L.P.	10.1	10-Q	May 5, 2022	001-34207	
10.26•	First Amendment to Lease, dated December 2, 2024, by and between Company and SPUS8 2100 Powell, L.P.					X
10.27†	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	
10.28^	First Amendment to Commercial Manufacturing and Supply Agreement, dated September 10, 2021, by and between Company and Baxter Pharmaceutical Solutions LLC	10.3	10-Q	November 4, 2021	001-34207	
10.29^	Second Amendment to Commercial Manufacturing and Supply Agreement, dated as of January 16, 2025, by and between Company and Baxter Pharmaceutical Solutions LLC d/b/a Simtra Biopharma Solutions					X
10.30^	Supply Agreement, dated February 10, 2025, between Company and West Pharmaceutical Services, Inc.					X
10.31^	Agreement, dated January 29, 2021 between Company and Coalition for Epidemic Preparedness Innovations	10.31	10-K	February 25, 2021	001-34207	
10.32^	First Amendment to Agreement, dated May 3, 2021, by and between Company and Coalition for Epidemic Preparedness Innovations	10.1	10-Q	August 4, 2021	001-34207	

10.33^	Waiver and Second Amendment to Agreement, dated effective as of April 27, 2023, by and between Company and Coalition for Epidemic Preparedness Innovations	10.2	10-Q	August 3, 2023	001-34207	
10.34^	Supply Agreement, dated effective April 1, 2021, between Company and Becton, Dickinson and Company	10.35	10-K	February 23, 2023	001-34207	
10.35^	Amendment #1 to Supply Agreement, dated September 28, 2022, between Company and Becton, Dickinson and Company	10.36	10-K	February 23, 2023	001-34207	
10.36^	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	
10.37^	Letter Agreement, dated August 30, 2022, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc., Clover Biopharmaceuticals (Hong Kong) Co., Limited and Sichuan Clover Biopharmaceuticals, Inc.	10.2	10-Q	November 3, 2022	001-34207	
10.38^	Letter Agreement No. 2, dated October 31, 2022, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited	10.4	10-Q	November 3, 2022	001-34207	
10.39^	Amendment No. 3 to Supply Agreement, effective August 15, 2022, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc., and Clover Biopharmaceuticals (Hong Kong) Co., Limited	10.37	10-K	February 23, 2023	001-34207	
10.40^	Amendment No. 4 to Supply Agreement, effective September 23, 2022, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc., and Clover Biopharmaceuticals (Hong Kong) Co., Limited	10.38	10-K	February 23, 2023	001-34207	
10.41^	Supply Agreement, dated July 1, 2021, by and between Company and Biological E. Limited	10.7	10-Q	August 4, 2021	001-34207	
10.42^	Amendment No. 1 to Supply Agreement, dated effective as of June 23, 2022, by and between Company and Biological E. Limited	10.1	10-Q	November 3, 2022	001-34207	

10.43^	Amendment No. 2 to Supply Agreement, dated effective as of September 30, 2022, by and between Company and Biological E. Limited	10.3	10-Q	November 3, 2022	001-34207	
10.44^	Amendment No. 3 to Supply Agreement, dated effective as of April 26, 2023, by and between Company and Biological E. Limited	10.1	10-Q	August 3, 2023	001-34207	
10.45^	Supply Agreement, effective as of September 7, 2023, by and between Company and Nitto Denko Avecia Inc.	10.1	10-Q	November 2, 2023	001-34207	
19.1	Insider Trading Policy					X
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Principal 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 Principal Executive Officer pursuant 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
97.1+	Dynavax Technologies Corporation Incentive Compensation Recoupment Policy	97.1	10-K	February 22, 2024	001-34207	

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 With Embedded Linkbase Document
EX—104	The cover page for this Annual Report on Form 10-K 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.

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information is of the type that the Registrant customarily and actually treats as private or confidential. 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.

• Certain schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

* 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 Registrant 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 and Director
(Principal Executive Officer)

Date: February 20, 2025

By: /s/ KELLY MACDONALD

Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: February 20, 2025

Signature	Title	Date
/s/ RYAN SPENCER **Ryan Spencer**	Chief Executive Officer and Director *(Principal Executive Officer)*	February 20, 2025
/s/ KELLY MACDONALD **Kelly MacDonald**	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 20, 2025
/s/ SCOTT MYERS **Scott Myers**	Chairman of the Board	February 20, 2025
/s/ FRANCIS R. CANO **Francis R. Cano, Ph.D.**	Director	February 20, 2025
/s/ JULIE EASTLAND **Julie Eastland**	Director	February 20, 2025
/s/ EMILIO EMINI **Emilio Emini, Ph.D.**	Director	February 20, 2025
/s/ DANIEL L. KISNER **Daniel L. Kisner, M.D.**	Director	February 20, 2025
/s/ BRENT MACGREGOR **Brent MacGregor**	Director	February 20, 2025
/s/ PETER R. PARADISO **Peter R. Paradiso**	Director	February 20, 2025
/s/ PEGGY V. PHILLIPS **Peggy V. Phillips**	Director	February 20, 2025
/s/ LAUREN SILVERNAIL **Lauren Silvernail**	Director	February 20, 2025
/s/ ELAINE D. SUN **Elaine D. Sun**	Director	February 20, 2025

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