

REFINITIV

# DELTA REPORT

## 10-K

DVAX - DYNAVAX TECHNOLOGIES CORP  
10-K - DECEMBER 31, 2024 COMPARED TO 10-K - DECEMBER 31, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	4685
CHANGES	260
DELETIONS	1476
ADDITIONS	2949

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, 2023

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

Corporation

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

33-0728374  
(IRS Employer  
Identification No.)

2100 Powell Street, Suite 720  
Emeryville, CA94608  
(510)  
(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

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 ☒ Yesx    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, 2023 June 30, 2024 as reported on the Nasdaq Global Select Market, was approximately \$0.9 billion. \$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 20, 2024 February 18, 2025, the registrant had outstanding 130,614,772 124,070,829 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's 2024 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, 2023 December 31, 2024.

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

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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 other product candidates, such as pipeline programs, including our shingles Tdap 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.

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## 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 Great Britain the United Kingdom and launched in the United States 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

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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 United States 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.

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- 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 Great Britain, 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

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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 debt 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 (defined below) 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.

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PART I

ITEM 1. BUSINESS

OUR COMPANY

We are a commercial stage biopharmaceutical company dedicated to developing and commercializing innovative vaccines in areas of significant unmet need, leveraging our demonstrated expertise and capabilities in vaccines and our proven, proprietary vaccine adjuvant technology, 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 leveraging our CpG 1018® adjuvant supply strategy 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 Great Britain 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 States, the European Union and Great Britain. 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 Great Britain 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 Tdap and plague. 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.
- Tdap vaccine program: Tdap-1018 is an investigational vaccine candidate intended for active booster immunization against tetanus, diphtheria, and pertussis ("Tdap").

Plague vaccine program: We are developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018 currently in a Phase 2 clinical trial in coll 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

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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 2023 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 \$213.3 million \$268.4 million of HEPLISAV-B product revenue in the U.S. during the year ended December 31, 2023 December 31, 2024, representing a 69% 26% increase compared to the year ended December 31, 2022 December 31, 2023. This increase was primarily driven by an increase in the adult hepatitis B vaccine market and HEPLISAV-B demand and market share gains in the U.S. in 2023, 2024, compared to 2022, 2023.
- HEPLISAV-B estimated total market share in the U.S. increased to approximately 42%, compared to approximately 35% 44% at the end of 2022.
- HEPLISAV-B estimated market share in the retail pharmacy segment increased to approximately 58%, 2024, compared to approximately 42% at the end of 2022. HEPLISAV-B estimated market share in the Integrated Delivery Networks ("IDNs") and Large Clinics segment increased to approximately 56%, compared to approximately 47% at the end of 2022.
- A supplemental Biologic License Application ("sBLA") for HEPLISAV-B vaccination of adults on hemodialysis is currently under priority review by We continue to expect the FDA with a Prescription Drug User Fee Act action date planned for May 13, 2024.
- Actively leveraging on the CDC's Advisory Committee on Immunization Practices ("ACIP") recommendation for hepatitis B vaccination in adults, which was published 2022, advising that all adults aged 19-59 should be vaccinated against hepatitis B. We believe this will help enable a significantly expanded total annual adult vaccine market opportunity of approximately \$800 million in the U.S. to expand to a peak of over \$900.0 million in annual sales by 2027, 2030, with HEPLISAV-B well positioned expected to achieve a majority 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.



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 than 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, Great Britain 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. Additionally, A, and PreHevbrio, a three-dose adult hepatitis B vaccine manufactured by VBI Vaccines Inc. ("VBI") is commercially available in multiple countries including the U.S. 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. While To the extent that we may explore additional territories outside of the U.S., the EU and Great Britain the United Kingdom to market HEPLISAV-B, in doing so we will likely face competition from these or other products and competitors.

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### Competition for our adjuvant supply supporting COVID-19 and our development pipeline including shingles, Tdap, 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 and VBI.

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 United States, 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 United States 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;

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- 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 NDA or BLA, ("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

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each successive clinical trial conducted during product development. Further, an independent institutional review board or IRB, ("IRB") for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice ("GCP") regulations and regulations for informed consent and privacy of individually identifiable information.

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

- *Phase 1.* Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically 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.

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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

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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, 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

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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 will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

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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 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.

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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

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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.

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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~~ 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

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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~~ 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~~ 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

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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. Great Britain (England, Scotland and Wales) The UK is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

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

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legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in 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, will determine how closely if implemented in their current form, bring the UK regulations will align 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 procedure.

In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and instead 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 marketing authorization to market products 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 authorization, effective in Great Britain the UK only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains 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. Accordingly, until the The Windsor Framework is implemented removes EU licensing

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processes and EU labeling and serialization requirements in relation to Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including and introduces a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may also rely on the International Recognition Procedure ("IRP"), when reviewing certain types of marketing authorization applications. This procedure is available UK-wide licensing process for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

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

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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

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federal criminal law enacted as part of, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. There are also federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

*Healthcare Privacy and Security Laws.* We **may be** **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 **United Kingdom’s** **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 **which went into effect in May 2018 introduced imposes** strict requirements **regarding 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, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 ("CCPA"), which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches.

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

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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.

For example, in Massachusetts, the MassHealth program has requested permission from the federal government to use commercial tools, such as a closed formulary, to negotiate more favorable rebate agreements from drug manufacturers.

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

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Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, (1) directs HHS the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain single-source drugs and 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 starting in fiscal year 2023, 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although they may be the Medicare Drug Price Negotiation Program is currently subject to legal challenges. In response 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 Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Drug Price Negotiation Program. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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 remain have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. Since January 2017, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, there have been a number of health reform measures by the Biden administration that have impacted 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 Biden 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. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.

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. This 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. On December 15, 2021, the Health Technology Regulation ("HTA Regulation"), was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the level of the EU level for joint clinical assessments in these areas. When The HTA Regulation has applied from January 12, 2025. Although it enters will enter into application 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 2025, 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 will be as of 2026. The HTA Regulation is intended to harmonize the clinical benefit assessment of HTA across the European Union, EU. Pricing and reimbursement decisions, based on these assessments, remain the responsibility of individual Member States. In light of the fact that the United Kingdom UK has left the EU, Regulation No 2021/2282 on

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HTA will does not apply in the United Kingdom, 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.

products, including, effective as of March 31, 2025, relaunching the Innovative Licensing and Access Pathway with more predictable timelines and closer involvement of the National Health Service.

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### MANUFACTURING

#### 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. Historically, we relied We rely on a single supplier to produce our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators. We also have a second qualified supplier to produce CpG 1018 adjuvant for our collaboration partners, to the extent needed. 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 buildings 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, 2023 December 31, 2024, we had 408 405 employees, comprised of 275 260 employees in the U.S., including 117 103 members of our field sales team located throughout the U.S., as well as 133 145 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 2023 2024 was 7% 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

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tenure among our employees is 3.0 3.7 years in the U.S. and 6.2 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

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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 Training

#### 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 2023, 32 2024, 29 leaders and key contributors completed a leadership development program, in addition to the 30 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.

In 2023, with support from

The development and engagement of our Diversity Leadership Team comprised of employees from across is among our company, we continued top priorities. We remain committed to advance living out our three Diversity, Equity, core values and Inclusion (DEI) Commitments:

- Fostering in creating a culture where all employees are every employee is recognized and appreciated for the unique individuals they are are. Our work i to these commitments focus on community outreach and engagement as well as efforts to support leadership excellence and career development for their accomplish

in the workplace.

- Providing education all employees. As a vaccine company, bettering public health is core to our employees on mission, and that responsibility reaches to bettering the negative effects of unconscious bias.
- Building and sustaining a team filled with a diversity of personal experiences, backgrounds, and perspectives.

In support lives of our three DEI Commitments, employees and broader communities.

In 2024, we again partnered with external DEI consultants to develop and deliver unconscious bias training to our newly hired employees were certified as a Great Place To Work for the second year in 2023. Further, a row. In addition, we train all hiring managers and those who interview candidates in the talent acquisition process on unconscious bias. Our human resources team oversees our DEI commitments and initiatives periodically and regularly reports to our senior management, including with respect to workforce demographic data. In 2023, we launched an internal DEI survey to all U.S. based employees, such that we can gather further information on our DEI initiatives and continue to work on our DEI commitments.

#### 2024 Initiative

In furtherance of these efforts, we identified, were named by Fortune as one of our corporate goals for 2024, further delivery on our DEI commitments by advancing key initiatives through each of our four DEI subcommittees: Recruitment, Employee Resource Groups, Community Involvement, and Development.

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](http://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](http://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*

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*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.*

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#### Risks Related to our Business and Capital Requirements

**HEPLISAV-B has been approved in the United States, the European Union and Great Britain 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 Great Britain 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

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required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

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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, Great Britain 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 year 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

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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. We 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, 2023** **December 31, 2024**, we had an accumulated deficit of **\$930.6 million** **\$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 1/2** clinical **trials in trial** for shingles and **Tdap**, **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 **Great Britain, 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, **Tdap 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

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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

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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.

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***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 [Great Britain 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. [Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement](#)

rates may be implemented in the future. Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market's acceptance of a price for HEPLISAV-B sufficient to achieve profitability, and future acceptance of such pricing.

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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 United Kingdom ("UK") 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 will apply applies as of January 2025, 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 foresees a three-year transitional period and will permit 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 will 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 United Kingdom UK has left the EU, Regulation No 2021/2282 on HTA will does not apply in the United Kingdom. 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 Pathways 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 United Kingdom 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.

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***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 **the study 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 **Great Britain, 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 **United Kingdom 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 **Great Britain, 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

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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.

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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

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research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be

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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 **Tdap, plague** and **influenza, 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, 2023** **December 31, 2024**, we had **\$742.3 million** **\$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. **We recorded** 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, 2023** **December 31, 2024**, we had an accumulated deficit of **\$930.6 million** **\$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.

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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

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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 **Great Britain, 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 **Great Britain, the United Kingdom**. Developing, seeking regulatory approval for and marketing our product candidates in or outside of the U.S., the European Union and **Great Britain 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 **Great Britain, 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 **Great Britain, 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

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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;

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- 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;

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- 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, 2023 December 31, 2024, we had U.S. federal and state NOL carryforwards of \$376.6 million \$293.5 million and \$283.9 million \$262.9 million, respectively. Of the \$376.6 million \$293.5 million U.S. federal NOL carryforwards, \$353.5 million \$293.1 million may be carried forward indefinitely with utilization limited to 80% of taxable income, and the remainder will begin to expire in 2024 2025. The state NOL carryforwards will begin to expire in 2024.

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.***

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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

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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.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to

Regulators in the United States or other countries due to are also increasingly scrutinizing certain personal data transfers and may impose data localization requirements, or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases for example, the Biden Administration's executive order Preventing Access to lawfully transfer personal data to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

Outside the United States, or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.

In the ordinary course of business, we may transfer personal data from the EEA and other jurisdictions to the United States or other countries. We may be unable to transfer personal data from Europe and other jurisdictions to the United States

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or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other certain jurisdictions have enacted data localization and cross-border data transfer laws, requiring data which could make it more difficult to be localized or limiting the transfer of personal data to other countries. information across jurisdictions. In particular, the EEA European Economic

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Area ("EEA") and the United Kingdom U.K. have significantly restricted the transfer of personal data to the United States and other countries whose privacy and data security laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations they believe not to offer an adequate level of their data localization and cross-border data transfer laws.

protection. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK U.K. to the United States in compliance with law, such as the EEA and UK's 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 there is no lawful manner for us we are unable to transfer implement a legal mechanism to ensure that our transfers of personal data from the EEA or the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer U.K. are too onerous, lawful, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, 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 inability 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 work limit our ability to collaborate with partners, vendors CROs and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, parties.

We are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some regulators in the EEA have ordered certain companies to suspend or permanently cease certain transfers of data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

On October 7, 2022, President Biden signed an Executive Order on "Enhancing Safeguards for United States Signals Intelligence Activities," which implements into United States law the agreement in principle announced in March 2022 on a new EU-U.S. Data Privacy Framework. However, if this new transatlantic data transfer framework is not adopted and we are unable to continue to rely on standard contractual clauses or alternative mechanisms of data transfers from the EEA to the United States, this may materially and adversely affect our business, financial condition, and results of operations.

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

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may be subject to contractual obligations and policies related to data privacy and security. We may also be bound by other 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 EU GDPR and UK GDPR, the CCPA, require our customers to impose specific contractual restrictions on their service providers.

Data We publish privacy policies, marketing materials and security laws are quickly changing, and other statements, such as compliance (and any perceived non-compliance) is costly. Although we endeavor to comply with all applicable certain certifications or self-regulatory principles, regarding data privacy and security obligations, security. If

these obligations policies, materials or statements are quickly changing found to be deficient, lacking in an increasingly stringent fashion, creating some uncertainty as to how to comply. Additionally, these obligations transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to differing applications and interpretations, face adverse consequences, which may be inconsistent or conflict among jurisdictions. If we or the third parties on which we rely fail, or include, but are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to, government 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; oversight, bans on processing personal data; data, orders to destroy or not use personal data; 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: loss of customers; to interruptions or stoppages in our business operations including (including clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our clinical trials; products, expenditure of time and resources to defend any claim or inquiry; adverse publicity; 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.

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***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.***

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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.

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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

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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, President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018 among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, the ACA has been subject to various health reform measures. For example, on August 16, 2022, President Biden signed 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 Biden second Trump administration will impact the ACA and our business.

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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, President Biden signed the American Rescue Plan Act of 2021 was signed into law, which eliminates eliminated the statutory Medicaid drug rebate cap, currently previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In addition, the American Taxpayer Relief Act

[Table of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.](#)[Contents](#)

Also, there has been heightened governmental scrutiny recently in the U.S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, for example, the IRA, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, (i) directs the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain drugs and 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. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting in 2023, 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 29, 2023 August 15, 2024, HHS announced the list agree-upon price of the first ten drugs that will be subject to price negotiations, although 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 pricing negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Drug Price Negotiation Program. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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

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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

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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 these 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.

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***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.

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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;

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- 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***

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***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.

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***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

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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.***

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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;

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- 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;

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- 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 tapering 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 &

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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, 2023, we had approximately \$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, including those issuable upon exercise of the outstanding warrants or conversion of the preferred stock, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

***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 debt 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

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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 **October January 1** through **December 31, 2023 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 **October January 1** through **December 31, 2023 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.

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***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.***

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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

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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,

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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

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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

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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. In 2020, we experienced a cybersecurity incident known as a phishing e-mail scam, and although we do not consider its impact on us to be material, if we are unable to prevent this or other such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of

reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures that

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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.

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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 process 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 process 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,

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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, 2023 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, 2025 2028
Manufacturing and office space	Düsseldorf, Germany	60,558 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.

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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".

"DVAX."

As of February 20, 2024 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, 2018 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.



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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

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Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

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	Approximate Dollar Value of Shares	
			Total Number of Shares Purchased as part of Publicly Announced Program	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]

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ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. The discussion should be read in conjunction with 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 Great Britain 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 \$800 million \$900.0 million in the U.S. by 2027, 2030, with HEPLISAV-B well positioned expected to achieve a majority 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 Tdap and plague, 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 2023, 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 Great Britain.

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

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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 Great Britain 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.

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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, 2023 December 31, 2024, HEPLISAV-B product revenue, net was \$213.3 million \$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, 2023 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, 2023 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). As of December 31, 2022, we recorded Advance Payments of \$107.7 million included in CEPI accrual. There were no deferred revenue balances related to the CEPI Agreement as of December 31, 2023.

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.

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 2022, 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.

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, 2023 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, 2023 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, 2023. We did not recognize CpG 1018 adjuvant net product revenue from Clover for the year ended December 31, 2023. We recognized CpG 1018 adjuvant net product revenue of \$288.0 million from Clover for the year ended December 31, 2022.

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

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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

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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 and, we had satisfied all delivery obligations thereunder.

As of December 31, 2023, 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 CEPI-Bio waiver and second amendment to the CEPI Agreement by and between us and CEPI (the "CEPI-Bio E Assignment Agreement 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, 2023 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.

We did not recognize CpG 1018 adjuvant net product revenue from Bio E for the year ended December 31, 2023. We recognized CpG 1018 adjuvant net product revenue of \$206.2 million from Bio E for the year ended December 31, 2022.

Past performance is not a reliable indicator of future performance, however, and future revenue and associated profit or loss may therefore vary significantly. Specifically, as our CpG 1018 adjuvant customers have purchased a significant quantity of CpG 1018 adjuvant as part of their initial COVID-19 vaccine development inventory, we currently expect minimal to no CpG 1018 adjuvant revenue in 2024 associated with these arrangements.

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.

#### Other

#### Convertible Notes

In May 2021, we issued \$225.5 million aggregate principal amount of 2.50% 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

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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.

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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 we transfer control of the promised goods is transferred to the customer, at the net sales price, which includes 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.

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

### Inventories

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.

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## 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. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 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, 2022](#) [December 31, 2023](#).

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### Revenues

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

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. We sell our CpG 1018 adjuvant to our collaboration partners for use in their development and/or potential commercialization of COVID-19 vaccines. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract.

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):

Increase

	Year Ended December 31,		(Decrease) from	
			2022 to 2023	
	2023	2022	\$	%
<b>Revenues:</b>				
HEPLISAV-B	\$ 213,295	\$ 125,937	\$ 87,358	69 %
CpG 1018 adjuvant	-	587,708	(587,708)	(100)%
Total product revenue, net	213,295	713,645	(500,350)	(70)%
Other revenue	18,989	9,038	9,951	110 %
Total revenues	\$ 232,284	\$ 722,683	\$ (490,399)	(68)%

	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
	2024	2023	\$	%
<b>Revenues:</b>				
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 \$87.4 million \$55.1 million for the year ended December 31, 2023 December 31, 2024 compared to the year ended December 31, 2022 December 31, 2023. Approximately \$76.5 million \$40.3 million of the increase was primarily 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 \$10.9 million \$14.8 million of the increase was due to higher net sales price.

There was no CpG 1018 adjuvant product revenue for the year ended December 31, 2023, as we completed all obligations and product delivery under our CpG 1018 adjuvant collaboration agreements as of December 31, 2022.

As our CpG 1018 adjuvant customers have purchased a significant quantity of CpG 1018 adjuvant as part of their initial COVID-19 vaccine development inventory, we currently expect minimal to no CpG 1018 adjuvant revenue in 2024. Long-term demand for CpG 1018 adjuvant supporting COVID-19 vaccines will be highly dependent on each customer's ability to commercialize in respective territories and geographies where their respective COVID-19 vaccine is approved for use.

Other revenue primarily includes revenue from our agreement with the DoD. During the year years ended December 31, 2023, December 31, 2024 and 2023, we recognized \$8.6 million and \$17.6 million of revenue from our agreement with the DoD, DoD, respectively. The increase decrease in other revenue was primarily driven by due to the advancement into a nonhuman primate challenge study initiated completion of the plague Phase 2 clinical trial during the third quarter of 2024, as compared to higher revenue earned in August early 2023 combined with the

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recognition of \$1.3 million license fee revenue on the achievement of a milestone in connection with a collaboration and license agreement with SIIPL.

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 and inventory costs to produce CpG 1018 adjuvant for our collaboration partners.

#### 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	2022	\$	%
<b>Cost of Sales - Product:</b>				
HEPLISAV-B	\$ 50,167	\$ 40,131	\$ 10,036	25 %

CpG 1018 adjuvant	-	222,022	(222,022)	(100)%
Total cost of sales - product	\$ 50,167	\$ 262,153	\$ (211,986)	(81)%

	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
	2024	2023	\$	%
<b>Cost of Sales - Product:</b>				
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 increased decreased by \$10.0 million \$0.7 million for the year ended December 31, 2023 December 31, 2024 compared to the year ended December 31, 2022 December 31, 2023. Approximately \$20.0 million of the increase The decrease was primarily due to higher sales volume driven by continued improvement in HEPLISAV-B market share, offset by a decrease of \$10.0 million due to lower per-unit manufacturing costs as the a result of previous process improvements.

There was no CpG 1018 adjuvant cost of sales-product for the year ended December 31, 2023, as we satisfied all delivery obligations under our CpG 1018 adjuvant collaboration agreements as of December 31, 2022. In addition, CpG 1018 adjuvant cost of sales-product for the year ended December 31, 2022, includes certain improvements and lower comparative one-time charges, totaling approximately \$45.4 million, comprising an inventory write-off partially offset by the increase in HEPLISAV-B sales volume.

[Table of \\$34.3 million in connection with cancelled orders and the reduction in demand associated with the Clover Supply Agreement, as amended, and \\$11.1 million in charges related to certain non-refundable pre-payments made to one of our CMOs regarding certain raw materials costs that are not likely to be manufactured into finished goods inventory.](#)[Contents](#)

### 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 2022 to 2023	
	2023	2022	\$	%
<b>Program Expenses:</b>				
HEPLISAV-B development	\$ 3,486	\$ 3,973	\$ (487)	(12)%
CpG 1018 adjuvant development	2,140	2,379	(239)	(10)%
Tetanus, diphtheria, and acellular pertussis	6,620	8,994	(2,374)	(26)%
Shingles	14,252	13,943	309	2 %
Plague (1)	8,319	4,065	4,254	105 %
Other	8,210	5,421	2,789	51 %
<b>Other Research and Development Expenses:</b>				
Facility costs	2,574	1,871	703	38 %
Non-cash stock-based compensation	9,285	5,954	3,331	56 %
Total research and development	\$ 54,886	\$ 46,600	\$ 8,286	18 %

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	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
	2024	2023	\$	%
<b>Program Expenses:</b>				
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 %
<b>Other Research and Development Expenses:</b>				
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 **adjuvanted with utilizing CpG 1018; 1018 adjuvant**. Under the agreement, we **are conducting** **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 **\$8.3 million** **\$6.7 million** for the year ended **December 31, 2023** **December 31, 2024** compared to the year ended **December 31, 2022** **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 lower clinical costs following the completion **non-recurrence** of the HEPLISAV-B dialysis study and lower other HEPLISAV-B related development costs. This was offset by a \$1.1 million expense related to an engineering run performed for product testing purposes in 2023.

2023, partially offset by continued investment in clinical research and collaboration.

- CpG 1018 adjuvant development costs decreased as supply agreements were fulfilled for our collaborators utilizing CpG 1018 adjuvant in 2022.
  - Shingles program costs increased as we completed activities related to the Phase 1 clinical trial, including presentation of study results at a medical conference 2023, and due to trial start up activities, including manufacturing of clinical materials to support the expected initiation of a Phase 1/2 clinical trial in the first half of 2024.
- Tdap costs decreased as we completed the Phase 1 clinical trial in early 2023, offset by an increase in activities to support initiation of a human challenge study expected the second half of 2024.
- Plague program costs increased compared to the previous year following our initiation of part 2 of the Phase 2 clinical trial in early 2023 and advancement into a nonh primate challenge study in August 2023.
- Other program costs increased as we **continue** **continued** to invest in product candidates utilizing our CpG 1018 adjuvant through discovery **and preclinical** efforts, **and through preclinical and clinical** **including external** collaborations.
- Non-cash stock-based compensation expense increased primarily due to **the need for increased** **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.

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### **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 insurance**; legal costs that include corporate and patent-related expenses; allocated facility **costs** **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 2022 to 2023	
	2023	2022	\$	%
<b>Selling, General and Administrative:</b>				
Compensation and related personnel costs	\$ 63,937	\$ 52,865	\$ 11,072	21 %
Outside services	47,374	41,049	6,325	15 %
Legal costs	3,981	2,223	1,758	79 %
Facility costs	8,585	12,153	(3,568)	(29) %
Non-cash stock-based compensation	29,069	23,118	5,951	26 %

Total selling, general and administrative	\$ 152,946	\$ 131,408	\$ 21,538	16 %
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	Year Ended December 31,		Increase (Decrease) from 2023 to 2024	
	2024	2023	\$	%
<b>Selling, General and Administrative:</b>				
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 \$21.5 million \$17.4 million for the year ended December 31, 2023 December 31, 2024 compared to the year ended December 31, 2022 December 31, 2023.

- Compensation and related personnel costs and non-cash stock-based compensation costs increased due to continued investments in headcount and personnel investments in our general across commercial and administrative and field sales functions to support business growth HEPLISAV-B and increased travel.

66 pipeline growth.

- Outside services increased due to more targeted commercial and marketing efforts to increase market share and maximize the opportunities presented by the ACIP's universal recommendation.
- Legal costs increased due to ongoing general legal activities supporting our continued growth and intellectual property activities supporting our clinical-stage pipeline.
- Facility costs decreased due to lower rent expense, as one of our leases expired in 2022, and lower depreciation expense related to furniture and fixtures fully depreciated in 2022.
- Non-cash stock-based compensation expense increased primarily due to increased headcount of our field sales team, continued investments in commercial efforts to increase HEPLISAV-B market share.

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

#### Gain on Sale of Assets

In July 2020, we sold assets related to our immuno-oncology compound, SD-101, which included intellectual property, clinical and non-clinical data, regulatory filings, clinical supply inventory and certain contracts to Surefire Medical Inc. d/b/a TriSalus Life Sciences ("TriSalus"). Pursuant to the Asset Purchase Agreement, we received \$5.0 million upon closing of the transaction and \$4.0 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional \$250.0 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound.

In each of September 2023 and May 2022, we received payment of \$1.0 million from TriSalus because it met a pre-commercialization milestone. In each of the third quarter of 2023 and second quarter of 2022, we recognized a gain on sale of SD-101 assets of \$1.0 million in our consolidated statements of operations.

#### 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. Change in fair value

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

	Year Ended December 31,		Increase (Decrease) from 2022 to 2023	
	2023	2022	\$	%
Interest income	\$ 31,993	\$ 7,912	\$ 24,081	304 %
Interest expense	\$ (6,757)	\$ (6,732)	\$ 25	(0) %
Sublease income	\$ 7,577	\$ 7,685	\$ (108)	(1) %
Change in fair value of warrant liability	\$ -	\$ 1,801	\$ (1,801)	(100) %
Other	\$ (152)	\$ 111	\$ (263)	(237) %

	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 change decrease in the fair value of warrant liability resulted primarily from the warrants, which expired in February 2022. There were no warrants outstanding as of December 31, 2023.
- The change in other sublease income is primarily due to foreign currency transactions and related fluctuations 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 value of the Euro compared to the U.S. dollar.

## Income Taxes

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

	Year Ended December 31,		Increase (Decrease) from 2022 to 2023	
	2023	2022	\$	%
Income tax expense	\$ 2,022	\$ 1,143	\$ 879	77 %
Effective income tax rate	(46.3) %	0.4 %	-	-

	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 \$0.9 million \$1.5 million for the year ended December 31, 2023 December 31, 2024 compared to the year ended December 31, 2022 December 31, 2023. Our income tax expense of \$2.0 million \$3.5 million and \$1.1 million \$2.0 million for the years ended December 31, 2023 December 31, 2024 and 2022 which is 2023, respectively, are primarily comprised of state and foreign income tax expense. Our effective tax rate for the year years ended December 31, 2023 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, 2023** **December 31, 2024**, we had **\$742.3 million** **\$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, 2023** **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, 2023**, **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, 2023**, **December 31, 2024** and **2023**, respectively. As of **December 31, 2023** **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.

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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, 2023** **December 31, 2024**, the aggregate principal amount of our Convertible Notes was \$225.5 million, excluding debt discount of **\$2.8 million** **\$1.6 million**. The Convertible Notes bear interest at a rate of **2.50%** **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, 2023** **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. For the year ended **December 31, 2022**, we recorded a net income of \$293.2 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

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During

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, a \$46.7 million of net adjustments from non-cash items, which included stock-based compensation, depreciation and amortization, amortization of right-of-use assets, non-cash interest expense, accretion amortization of discounts premiums (accretion of discounts) on marketable securities, and 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 an increase of \$19.8 million in accrued and other liabilities. By comparison, during the year ended December 31, 2022, we generated \$62.7 million of cash from our operations, which consisted of our net income of \$293.2 million, a \$69.0 million of net adjustments from non-cash items, which included stock-based compensation, change in fair value of warrant liability, non-cash interest expense, depreciation and amortization, amortization of right-of-use assets, accretion of discount on marketable securities and inventory write-off, and approximately \$298.4 million net changes from operating assets and liabilities, which included \$349.9 million decrease in deferred revenue due to the fulfillment of our obligations to deliver CpG 1018 adjuvant to our collaboration partners, \$24.8 million decrease in accrued liabilities and other liabilities, \$159.7 million decrease in prepaid manufacturing, which converted into CpG 1018 adjuvant inventory during 2022, \$32.4 million increase in inventories and \$21.1 million decrease in CEP! accrual. Overall, cash provided by our operations during the year ended December 31, 2023 increased December 31, 2024 decreased by \$37.8 million \$34.1 million compared to the same period in December 31, 2022 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, 2023 December 31, 2024, net cash used in investing activities was \$153.9 million \$18.0 million compared to \$316.0 million \$153.9 million of cash used in investing activities for the year ended December 31, 2022 December 31, 2023. Cash used in investing activities during the year ended December 31, 2023 December 31, 2024 included \$150.8 million \$11.7 million of net purchases of marketable securities, compared to \$309.9 million \$150.8 million of net purchases of marketable securities for the year ended December 31, 2022 December 31, 2023.

During the year ended December 31, 2023 December 31, 2024, net cash used in financing activities was \$102.0 million compared to \$1.4 million of cash provided by financing activities was \$1.4 million. During for the year ended December 31, 2022, net cash provided by December 31, 2023. Cash used in financing activities was \$19.5 million, 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. Cash provided by financing activities for the year ended December 31, 2022 included proceeds of \$8.5 million from warrants exercised, and proceeds of \$11.1 million from the exercise of stock options and employee stock purchase plan.

#### **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

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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 \$7.6 million \$5.0 million, \$7.7 million \$7.6 million and \$7.7 million for the years ended December 31,

2023 December 31, 2024, 2022 2023 and 2021, 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

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In May 2021 and we issued an additional \$25.5 million of the Convertible Notes. As of December 31, 2023 December 31, 2024, the aggregate principal amount of our Convertible Notes was \$225.5 million, excluding debt discount of \$2.8 million \$1.6 million. The Convertible Notes bear interest at a rate of 2.50% 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.

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

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, 2026 December 31, 2029, and there are certain limits on the number of batches that Baxter is required to produce. As of December 31, 2023 December 31, 2024, our aggregate minimum commitment under the Baxter Agreement was \$11.4 million \$17.0 million within the next 12 months, and \$24.5 million \$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, 2023 December 31, 2024, our aggregate minimum commitment for the supply of CpG 1018 adjuvant under the Avecia Supply Agreement was \$7.4 million \$8.2 million for the 12 months following December 31, 2023 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.

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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 million \$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, 2023 December 31, 2024.

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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, compared to \$4.1 million or \$5.1 million as of December 31, 2022, 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, 2023 December 31, 2024 and 2022 2023 was a \$3.0 million \$5.3 million and \$4.0 million \$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, 2023 December 31, 2024 and 2022, 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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

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<a href="#">Consolidated Statements of Comprehensive Income (Loss) Income</a>	77	77
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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, 2023** **December 31, 2024** and **2022, 2023**, the related consolidated statements of operations, comprehensive **income** (loss) **income**, stockholders' equity and cash flows for each of the three years in the period ended **December 31, 2023** **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, 2023** **December 31, 2024** and **2022, 2023**, and the results of its operations and its cash flows for each of the three years in the period ended **December 31, 2023** **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, 2023** **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 22, 2024** **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, 2023** **December 31, 2024**, the Company's net product revenues for HEPLISAV-B were **\$213.3 million** **\$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

or reserves for HEPLISAV-B product returns under its contracts with wholesalers and specialty distributors (collectively, "Customers") was challenging because (1) the calculation involves management assumptions about inventory remaining in the distribution channel (i.e., units held by Customers) as of the balance sheet date 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.

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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 **Customers' units in the channel as of the balance sheet date.**

**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 **agreements with significant Customers to validate 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 and compared the shipment reports to Customers sell through information to assess the extent of inventory in the distribution channel, 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 22, 2024 20, 2025

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DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

December 31,	
2023	2022

<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents	\$	150,279	\$ 202,004
Marketable securities available-for-sale		592,023	422,391
Accounts receivables, net of allowance for doubtful accounts of \$12,313 and \$0 at December 31, 2023 and December 31, 2022, respectively		40,607	145,130
Other receivables		3,926	2,385
Inventories		53,290	59,446
Prepaid expenses and other current assets		18,995	85,629
<b>Total current assets</b>		<b>859,120</b>	<b>916,985</b>
Property and equipment, net		37,297	37,596
Operating lease right-of-use assets		24,287	25,745
Goodwill		2,067	2,006
Other assets (Note 9)		74,325	3,518
<b>Total assets</b>	<b>\$</b>	<b>997,096</b>	<b>\$ 985,850</b>
<b>Liabilities and stockholders' equity</b>			
<b>Current liabilities:</b>			
Accounts payable	\$	5,245	\$ 3,211
Accrued research and development		2,982	4,775
CEPI accrual (Note 9)		-	107,738
Accrued liabilities (Note 7)		49,448	30,719
Other current liabilities		4,520	3,631
<b>Total current liabilities</b>		<b>62,195</b>	<b>150,074</b>
Convertible Notes, net of debt discount of \$2,802 and \$3,922 at December 31, 2023 and December 31, 2022, respectively (Note 10)		222,698	221,578
Long-term portion of lease liabilities		29,720	32,801
CEPI accrual long-term (Note 9)		60,337	-
Other long-term liabilities		74	384
<b>Total liabilities</b>		<b>375,024</b>	<b>404,837</b>
<b>Commitments and contingencies (Note 8)</b>			
<b>Stockholders' equity:</b>			
Preferred stock: \$0.001 par value, 5,000 shares authorized at December 31, 2023, and 2022; zero shares outstanding at December 31, 2023 and 2022		-	-
Common stock: \$0.001 par value; 278,000 shares authorized at December 31, 2023 and 2022; 129,530 shares and 127,604 shares issued and outstanding at December 31, 2023 and 2022, respectively		130	128
Additional paid-in capital		1,554,634	1,510,518
Accumulated other comprehensive loss		(2,108)	(5,438)
Accumulated deficit		(930,584)	(924,195)
<b>Total stockholders' equity</b>		<b>622,072</b>	<b>581,013</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$</b>	<b>997,096</b>	<b>\$ 985,850</b>

	December 31,	
	2024	2023
<b>Assets</b>		
<b>Current assets:</b>		
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	<u>\$ 986,256</u>	<u>\$ 997,096</u>
<b>Liabilities and stockholders' equity</b>		
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	<u>\$ 986,256</u>	<u>\$ 997,096</u>

See accompanying notes.

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

	Year Ended December 31,		
	2023	2022	2021
<b>Revenues:</b>			
Product revenue, net	\$ 213,295	\$ 713,645	\$ 437,099
Other revenue	18,989	9,038	2,343
<b>Total revenues</b>	<u>232,284</u>	<u>722,683</u>	<u>439,442</u>
<b>Operating expenses:</b>			

Cost of sales - product	50,167	262,153	173,572
Research and development	54,886	46,600	32,228
Selling, general and administrative	152,946	131,408	100,156
Gain on sale of assets (Note 8)	(1,000)	(1,000)	(1,000)
Bad debt expense (Note 9)	12,313	-	-
<b>Total operating expenses</b>	<b>269,312</b>	<b>439,161</b>	<b>304,956</b>
<b>(Loss) income from operations</b>	<b>(37,028)</b>	<b>283,522</b>	<b>134,486</b>
<b>Other (expense) income:</b>			
Interest income	31,993	7,912	140
Interest expense	(6,757)	(6,732)	(11,176)
Sublease income	7,577	7,685	7,735
Loss on debt extinguishment (Note 11)	-	-	(5,232)
Change in fair value of warrant liability (Note 14)	-	1,801	(49,354)
Other	(152)	111	922
<b>Net (loss) income before income taxes</b>	<b>(4,367)</b>	<b>294,299</b>	<b>77,521</b>
<b>Provision for income taxes</b>	<b>(2,022)</b>	<b>(1,143)</b>	<b>(808)</b>
<b>Net (loss) income</b>	<b>\$ (6,389)</b>	<b>\$ 293,156</b>	<b>\$ 76,713</b>
<b>Undistributed earnings allocated to participating securities</b>	<b>-</b>	<b>(283)</b>	<b>(4,569)</b>
<b>Net (loss) income allocable to common stockholders</b>	<b>\$ (6,389)</b>	<b>\$ 292,873</b>	<b>\$ 72,144</b>
<b>Net (loss) income per share allocable to common stockholders</b>			
Basic	\$ (0.05)	\$ 2.32	\$ 0.62
Diluted	\$ (0.05)	\$ 1.97	\$ 0.57
<b>Weighted-average shares used in computing net (loss) income per share allocable to common stockholders:</b>			
Basic	128,733	126,398	116,264
Diluted	128,733	150,797	133,006

	Year Ended December 31,		
	2024	2023	2022
<b>Revenues:</b>			
Product revenue, net	\$ 268,430	\$ 213,295	\$ 713,645
Other revenue	8,816	18,989	9,038
<b>Total revenues</b>	<b>277,246</b>	<b>232,284</b>	<b>722,683</b>
<b>Operating expenses:</b>			
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	-
<b>Total operating expenses</b>	<b>281,368</b>	<b>269,312</b>	<b>439,161</b>
<b>(Loss) income from operations</b>	<b>(4,122)</b>	<b>(37,028)</b>	<b>283,522</b>
<b>Other (expense) income:</b>			
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
<b>Net income (loss) before income taxes</b>	<b>30,855</b>	<b>(4,367)</b>	<b>294,299</b>
<b>Provision for income taxes</b>	<b>(3,546)</b>	<b>(2,022)</b>	<b>(1,143)</b>
<b>Net income (loss)</b>	<b>\$ 27,309</b>	<b>\$ (6,389)</b>	<b>\$ 293,156</b>
<b>Undistributed earnings allocated to participating securities</b>	<b>-</b>	<b>-</b>	<b>(283)</b>

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.

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## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) INCOME

(In thousands)

	Year Ended December 31,		
	2023	2022	2021
Net (loss) income	\$ (6,389)	\$ 293,156	\$ 76,713
Other comprehensive income (loss), net of tax:			
Change in unrealized loss on marketable securities available-for-sale	2,251	(1,407)	(30)
Cumulative foreign currency translation adjustments	1,079	(1,765)	(2,509)
Total other comprehensive income (loss)	3,330	(3,172)	(2,539)
Total comprehensive (loss) income	\$ (3,059)	\$ 289,984	\$ 74,174

	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.

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## DYNAVAX TECHNOLOGIES CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Amount	Shares	Par Amount				
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

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Amount	Shares	Par Amount				
Balances at December 31, 2020	110,190	\$ 110	4	\$ -	\$ 1,352,374	\$ 273	\$ (1,294,064)	\$ 58,693
Conversion of preferred stock	4,140	4	(4)	-	(4)	-	-	-
Issuance of common stock upon exercise of stock options	1,035	2	-	-	6,682	-	-	6,684
Issuance of common stock upon release of restricted stock awards	525	-	-	-	(107)	-	-	(107)
Issuance of common stock under Employee Stock Purchase Plan	217	-	-	-	841	-	-	841
Issuance of common stock upon exercise of warrants	3,959	4	-	-	59,884	-	-	59,888

Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (Note 14)	2,879	3	-	-	28,153	-	-	28,156
Issuance of capped call options (Note 10)	-	-	-	-	(27,240)	-	-	(27,240)
Stock compensation expense	-	-	-	-	21,285	-	-	21,285
Total other comprehensive loss	-	-	-	-	-	(2,539)	-	(2,539)
Net income	-	-	-	-	-	-	76,713	76,713
Balances at December 31, 2021	122,945	\$ 123	-	\$ -	\$ 1,441,868	\$ (2,266)	\$ (1,217,351)	\$ 222,374
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

See accompanying notes.

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

	Year Ended December 31,		
	2023	2022	2021
<b>Operating activities</b>			
Net (loss) income	\$ (6,389)	\$ 293,156	\$ 76,713
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	4,342	3,812	4,296

Amortization of right-of-use assets	2,934	2,856	2,762
Inventory write-off	-	34,288	2,588
Amortization of premiums (accretion of discounts) on marketable securities	(16,555)	(4,181)	470
Loss on debt extinguishment	-	-	5,232
Change in fair value of warrant liability	-	(1,801)	49,354
Stock-based compensation expense	42,592	32,915	21,285
Non-cash interest expense	1,120	1,088	1,608
Gain on sale of assets	(1,000)	(1,000)	(1,000)
Bad debt expense (Note 9)	12,313	-	-
Changes in operating assets and liabilities:			
Accounts and other receivables, net	43,268	(15,699)	(109,155)
Inventories	3,909	(32,399)	(234)
Prepaid manufacturing	-	159,655	(130,232)
Prepaid expenses and other current assets	(4,673)	(11,865)	(64,558)
Other assets	570	87	175
Accounts payable	1,952	691	(767)
CEPI accrual (Note 9)	-	(21,110)	128,848
Lease liabilities	(3,629)	(3,125)	(3,234)
Deferred revenue	-	(349,864)	311,652
Accrued and other liabilities	19,809	(24,788)	39,725
Net cash provided by operating activities	100,563	62,716	335,528
Investing activities			
Purchases of marketable securities	(636,921)	(632,306)	(164,928)
Proceeds from maturities and redemptions of marketable securities	486,097	322,450	187,630
Purchases of property and equipment, net	(4,104)	(7,139)	(9,477)
Proceeds from sale of assets, net of transaction costs	1,000	1,000	1,000
Net cash (used in) provided by investing activities	— (153,928)	— (315,995)	— 14,225
Financing activities			
Proceeds from issuances of common stock, net	-	-	28,156
Proceeds from issuance of Convertible Notes, net	-	-	219,822
Purchases of capped call options	-	-	(27,240)
Repayment of long-term debt	-	-	(190,194)
Proceeds from warrants exercises	-	8,455	17,814
Proceeds from exercise of stock options and/or release of restricted stock awards, net	6,360	9,639	6,577
Proceeds from Employee Stock Purchase Plan	1,535	1,431	841
Payments for taxes related to net share settlement of RSUs	(6,509)	-	-
Net cash provided by financing activities	1,386	19,525	55,776
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	324	(443)	(1,431)
Net (decrease) increase in cash and cash equivalents, and restricted cash	(51,655)	(234,197)	404,098
Cash and cash equivalents, and restricted cash at beginning of year	202,211	436,408	32,310
Cash and cash equivalents, and restricted cash at end of year	\$ 150,556	\$ 202,211	\$ 436,408
Supplemental disclosure of cash flow information			
Cash paid during the year for income taxes	\$ 2,014	\$ 2,208	\$ 1,312
Cash paid during the year for interest	\$ 5,638	\$ 5,638	\$ 9,815
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	\$ 299	\$ 1,015	\$ 591
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 1,332	\$ 2,848	\$ 2,468

	Year Ended December 31,		
	2024	2023	2022
<b>Operating activities</b>			
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
<b>Investing activities</b>			
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)
<b>Financing activities</b>			
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
<b>Supplemental disclosure of cash flow information</b>			
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.

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## DYNAVAX TECHNOLOGIES CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 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 Great Britain 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 Tdap, 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 (loss) in stockholders' equity.

As of December 31, 2023 December 31, 2024 and 2022, 2023, the cumulative translation adjustments balance was \$(3.0) million balances reflected losses of \$5.3 million and \$(4.0) million, \$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, 2023 December 31, 2024, 2022 2023 and 2021, 2022, we reported an unrealized foreign currency translation (loss) gain (loss) of \$1.1 \$(2.4) million, \$(1.8) million \$1.1 million and \$(2.5) \$(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, 2023 December 31, 2024, 2022 2023 and 2021, 2022, we reported a gain (loss) gain of \$(0.1) million, \$0.1 \$0.3 million, \$(0.1) million and \$0.9 million, \$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

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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% 10% of total net assets as of December 31, 2023 December 31, 2024 and 2022. 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. (loss), 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, \$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, 2023 December 31, 2024 and 2022, 2023, three customers collectively represented approximately 81% 97% and 78% 81% of our HEPLISAV-B trade receivable balance, respectively. As of December 31, 2023, we had no CpG 1018 adjuvant trade receivable balance. As of December 31, 2022, one customer represented approximately 100% of our CpG 1018 adjuvant trade receivable balance.

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, 2023, December 31, 2024 and 2022, 2023, represented 31%, 26% and 34%, 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, 2023, December 31, 2024 and 2022, 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.

### CpG 1018 Adjuvant 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 year ended December 31, 2023, there was no remaining CpG 1018 adjuvant inventory balance. For the year ended December 31, 2022, we recorded \$34.3 million of inventory write-off to cost of sales - product, in connection with cancelled orders and the reduction in demand for CpG 1018 adjuvant reflected in the Clover Supply Agreement, as amended (See Note 9).

## 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. If 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

### 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

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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 **Accounting Standards Codification** 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 **test** 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% 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”).

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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.

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

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

#### **Product Revenue, Net – CpG 1018 Adjuvant**

We also sell our innovative adjuvant, CpG 1018 adjuvant, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. We have determined that our collaboration partners meet the definition of Customers under ASC 606. Therefore, we accounted for our CpG 1018 adjuvant sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer. Because the timing between the recognition of revenue for product sales and the receipt of payment is less than one year, there is no significant financing component on the related receivables. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

Overall, product revenue, net - CpG 1018 adjuvant, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. Our CpG 1018 adjuvant customers have purchased a significant quantity of CpG 1018 adjuvant as part of their initial COVID-19 vaccine development inventory. Accordingly, we did not recognize CpG 1018 adjuvant net product revenue during the year ended December 31, 2023.

#### **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

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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

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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

### Accounting Standards Update 2016-13

In June 2016, November 2023, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*, which was codified in Accounting Standards Codification ASC 326, *Financial Instruments – Credit Losses*. The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. Because we were a smaller reporting company based on the most recent determination as of November 15, 2019, ASC 326 became effective for us for fiscal years beginning after December 15, 2022. As such, we adopted ASC 326 effective January 1, 2023, utilizing the modified retrospective transition method. Upon adoption, we updated our impairment model to utilize a forward-looking current expected credit losses ("CECL") model in place of the incurred loss methodology for financial instruments measured at amortized cost, primarily including our accounts receivable and contract asset. In relation to AFS debt securities, the guidance eliminates the concept of "other-than-temporary" impairment, and instead focuses on determining whether any impairment is a result of a credit loss or other factors. The adoption of ASC 326 did not have a material impact on our consolidated financial statements as of the adoption date.

In November 2023, 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 are currently evaluating adopted ASU 2023-07 in the fiscal year beginning January 1, 2024. The adoption of this guidance did not have a material impact of adopting ASU 2023-07, 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

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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, 2023 December 31, 2024 and 2022.

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.

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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, 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
<b>Total assets</b>	<b>\$ 131,635</b>	<b>\$ 599,477</b>	<b>\$ -</b>	<b>\$ 731,112</b>

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>December 31, 2022</b>				
<b>Assets</b>				
Money market funds	\$ 172,418	\$ -	\$ -	\$ 172,418
U.S. treasuries	-	42,308	-	42,308
U.S. government agency securities	-	88,032	-	88,032
Corporate debt securities	-	292,051	-	292,051
<b>Total assets</b>	<b>\$ 172,418</b>	<b>\$ 422,391</b>	<b>\$ -</b>	<b>\$ 594,809</b>

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>December 31, 2024</b>				
<b>Assets</b>				
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
<b>Total assets</b>	<b>\$ 83,726</b>	<b>\$ 617,951</b>	<b>\$ -</b>	<b>\$ 701,677</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>December 31, 2023</b>				
<b>Assets</b>				
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
<b>Total assets</b>	<b>\$ 131,635</b>	<b>\$ 599,477</b>	<b>\$ -</b>	<b>\$ 731,112</b>

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.

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

Warrants were issued in connection with the underwritten public offering in August 2019 and are accounted for as a derivative liability at fair value (See Note 14). The fair value of the warrant liability was estimated using the Black-Scholes model, which requires assumptions such as expected term, expected volatility and risk-free interest rate. These assumptions are subjective and require judgment to develop. Expected term is estimated using the full remaining contractual term of the warrants. We determine expected volatility based on our historical common stock price volatility. The warrant liability was classified as a Level 3 instrument as its value was based on unobservable inputs that are supported by little or no market activity. As of December 31, 2022, all 1,882,600 of the outstanding warrants as of December 31, 2021 have been exercised or expired.

The following table provides a summary of changes in the fair value warrant liability for year ended December 31, 2022 (in thousands):

\$ 18,016

Balance at December 31, 2021	
Decrease in fair value of warrants exercised	(1,801)
Warrants exercised or expired	(16,215)
Balance at December 31, 2022	\$ -

#### 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,		
	2023	2022	2021
Cash and cash equivalents	\$ 150,279	\$ 202,004	\$ 436,189
Restricted cash <sup>(1)</sup>	277	207	219
Total cash and cash equivalents, and restricted cash shown in the consolidated statements of cash flows	\$ 150,556	\$ 202,211	\$ 436,408

	December 31,		
	2024	2023	2022
Cash and cash equivalents	\$ 95,883	\$ 150,279	\$ 202,004
Restricted cash <sup>(1)</sup>	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).

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>December 31, 2023</b>				
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
<b>December 31, 2022</b>				
Cash and cash equivalents:				

Cash	\$ 29,586	\$ -	\$ -	\$ 29,586
Money market funds	172,418	-	-	172,418
Total cash and cash equivalents	202,004	-	-	202,004
Marketable securities available-for-sale:				
U.S. treasuries	42,502	-	(194)	42,308
U.S. government agency securities	88,429	-	(397)	88,032
Corporate debt securities	292,865	12	(826)	292,051
Total marketable securities available-for-sale	423,796	12	(1,417)	422,391
Total cash and cash equivalents, and marketable securities	\$ 625,800	\$ 12	\$ (1,417)	\$ 624,395

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>December 31, 2024</b>				
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

<b>December 31, 2023</b>				
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, 2023	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	\$ 440,131	\$ 440,104
Mature after one year through two years	151,046	151,919
	\$ 591,177	\$ 592,023

	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. Available-for-sale 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. Commencing with our adoption of ASC 326 on January 1, 2023, we 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, (loss), 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, 2023 December 31, 2024 and 2022, 2023. We do not intend to sell, and are not required to sell, the investments that are in an

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unrealized loss position before recovery of their amortized cost basis. For the year ended December 31, 2023 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, 2023 December 31, 2024. As such, there have been no declines in fair value that have been identified as a credit-related impairment.

## 5.Inventories

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The following table presents inventories (in thousands):

	December 31,	
	2023	2022
Raw materials	\$ 27,256	\$ 25,517
Work-in-process	18,954	23,934
Finished goods	7,080	9,995
Total	\$ 53,290	\$ 59,446

	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,	
		2023	2022
Manufacturing equipment	5-13	\$ 15,752	\$ 15,139
Lab equipment	5-13	2,827	2,360
Computer equipment	3	5,060	4,720
Furniture and fixtures	3-13	2,467	2,464
Leasehold improvements	2-12	37,201	28,822
Assets in progress		5,822	11,613
		69,129	65,118
Less accumulated depreciation and amortization		(31,832)	(27,522)
Total		\$ 37,297	\$ 37,596

	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 \$4.3 million, \$3.8 million \$4.6 million, \$4.3 million and \$4.3 million \$3.8 million for the years ended December 31, 2023 December 31, 2024, 2023 and 2022, and 2021, respectively.

## 7. Current Accrued Liabilities

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

	December 31,	
	2023	2022
Payroll and related expenses	\$ 17,069	\$ 14,261
Revenue reserve accruals	21,004	10,552
Accrued inventory	4,456	2,209
Other accrued liabilities	6,919	3,697
Total	\$ 49,448	\$ 30,719

	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

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## 8. Commitments and Contingencies

### Leases

### 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 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 \$7.6 million, \$7.7 million \$5.0 million, \$7.6 million and \$7.7 million \$7.7 million for the years ended December 31, 2023 December 31, 2024, 2023 and 2022, respectively. Both the net loss on sublease termination and 2021, respectively. Sublease the sublease income is are included net in other "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% 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,		
	2023	2022	2021
Operating lease expense	\$ 5,563	\$ 6,222	\$ 6,265

	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, 2023 December 31, 2024, 2023, and 2022 was \$7.6 million, \$7.2 million, and 2021 was \$7.2 million, \$6.8 million, and \$7.0 million, \$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

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	December 31,	
	2023	2022
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	\$ 4,496	\$ 3,631
Long-term portion of lease liabilities	29,720	32,801
Total operating lease liabilities	\$ 34,216	\$ 36,432

As of December 31, 2023 December 31, 2024, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	December 31,	
	Sublease Income	Operating Lease Liabilities
2024	\$ 5,684	\$ 7,605
2025	5,854	6,980
2026	6,030	6,122
2027	6,211	6,052
2028	6,397	6,215
Thereafter	15,103	15,062
Total	\$ 45,279	48,036
Less:		
Present value adjustment		(13,820)

Total		\$	34,216
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,	
	2023	2022
Weighted average remaining lease term	6.7 years	7.6 years
Weighted average discount rate	10.1 %	10.1 %

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

## Commitments

### Commitments

As of **December 31, 2023** **December 31, 2024**, our material non-cancelable purchase and other commitments for the supply of HEPLISAV-B totaled **\$43.4 million**. **\$80.5 million**. The following summarizes our material purchase commitments at **December 31, 2023** **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)	Years ending December 31,	(in thousands)
2024	\$ 18,866		
2025	11,983		
2026	12,516		
2027	-		
2028	-		
2029			
Thereafter	-		
Total	\$ 43,365		

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

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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, 2023** **December 31, 2024**, our aggregate minimum commitment for the supply of CpG 1018 adjuvant under the Avecia Supply Agreement was **\$7.4 million** **\$8.2 million** within the next 12 months. **As of December 31, 2022, we had no non-cancelable purchase and other commitments for the supply of CpG 1018 adjuvant.**

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, 2023** **December 31, 2024**, the aggregate principal amount of our convertible senior notes ("Convertible Notes") was **\$225.5 million**, **\$225.5 million**, excluding debt discount of **\$2.8 million** **\$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** **€0.2 million** (Euros). The letter of credit remained outstanding through **December 30, 2023** **December 31, 2024** and was collateralized by a certificate of deposit for **€0.2 million**, **€0.2 million**, which has been included in restricted cash in the consolidated balance sheets as of **December 31, 2023** **December 31, 2024** and **2022**.

**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%** **50%** of the first **\$50 million** **\$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** **\$2.5 million** to Holdings in August 2020. In each of September 2021, May 2022 and September 2023, we received **\$1.0 million** **\$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** **\$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.

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## **Contingencies**

### **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.

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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~~ \$47.4 million of Bio E accounts receivable.

Through ~~December 31, 2023~~ December 31, 2024, we received Advance Payments totaling approximately ~~\$175.0 million~~ \$175.0 million pursuant to the CEPI Agreement, of which ~~\$67.3 million~~ \$67.3 million have been repaid and ~~\$47.4 million~~ \$47.4 million have been forgiven (as discussed above). As of ~~December 31, 2023~~ December 31, 2024, remaining Advance Payments totaling ~~\$60.3 million~~ \$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). As of December 31, 2022, we recorded Advance Payments of \$107.7 million included in CEPI accrual. There were no deferred revenue balances related to the CEPI Agreement as of ~~December 31, 2023~~ December 31, 2024 and ~~December 31, 2022~~ 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 2022~~, 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.

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The contract asset of ~~\$71.3 million~~ \$71.3 million relating to Clover was included in other current assets as of ~~December 31, 2022~~. The contract asset was subsequently reclassified to other assets (long term) ~~December 31, 2024~~ and remains classified in other assets (long term) as of December 31, 2023. The contract asset was ~~reclassified to 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~~ \$60.3 million relating to Clover are recorded in CEPI accrual long-term in our consolidated balance sheets as of ~~December 31, 2023~~ 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, 2023~~ December 31, 2024 and December 31, 2022. We did not recognize CpG 1018 adjuvant net product revenue from Clover for the year ended December 31, 2023. We recognized CpG 1018 adjuvant net product revenue of \$288.0 million for the year ended December 31, 2022.

Additionally, during the year ended December 31, 2022 and in connection with amendments to the Clover Supply Agreement, which reduced or cancelled certain orders for CpG 1018 adjuvant, we recorded an inventory write-off of \$34.3 million of excess CpG 1018 adjuvant raw materials and finish goods inventory. This excess inventory write-off was reflected as a charge to cost of sales – product, in the consolidated statements of operations for the year ended December 31, 2022.

#### 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

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

As of ~~December 31, 2023~~ December 31, 2024, we had no accounts receivable balance from Bio E. During the first quarter of ~~in~~ 2023, we recorded an allowance for doubtful accounts of ~~\$12.3 million~~, \$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~~ ~~\$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~~ ~~\$47.4 million~~ of Bio E accounts receivable. Pursuant to the Bio E Amendment No. 3, we collected ~~\$14.5 million~~ ~~\$14.5 million~~ from Bio E (including ~~\$13.5 million~~ ~~\$13.5 million~~ in April 2023 and ~~\$1.0 million~~ ~~\$1.0 million~~ in August 2023). Accordingly, as of ~~December 31, 2023~~ ~~December 31, 2024~~, the CEPI-Bio E Assignment Agreement resulted in: (i) no accounts receivable balance, and (ii) the derecognition of ~~\$47.4 million~~ ~~\$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~~ ~~\$5.5 million~~ in the event that Bio E receives at least ~~\$125.0 million~~ ~~\$125.0 million~~, or ~~\$12.3 million~~ ~~\$12.3 million~~ in the event that Bio E receives at least ~~\$250.0 million~~ ~~\$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.

~~We did not recognize CpG 1018 adjuvant net product revenue from Bio E for the year ended December 31, 2023. We recognized CpG 1018 adjuvant net product revenue of \$206.2 million for the year ended December 31, 2022.~~

## 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~~ ~~\$22.0 million~~ over two and a half years. Under the agreement, we are

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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~~ ~~\$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, 2023~~ ~~December 31, 2024~~ and ~~2022~~, 2023, we recognized revenue of ~~\$17.6 million~~ ~~\$8.6 million~~ and ~~\$8.8 million~~, ~~\$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~~ ~~\$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~~ ~~\$5.7 million~~, were ~~\$219.8 million~~ ~~\$219.8 million~~. We used ~~\$190.2 million~~ ~~\$190.2 million~~ of the net proceeds to retire our previous loan agreement with CRG Servicing LLC and ~~\$27.2 million~~ ~~\$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 ~~2.50%~~ ~~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~~ ~~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~~ ~~\$1,000~~ principal amount of the Convertible Notes, which is equivalent to an initial conversion price of approximately ~~\$10.47~~ ~~\$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%~~ ~~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~~ ~~\$1,000~~ principal amount of the Convertible Notes for each

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trading day of the measurement period was less than ~~98%~~ ~~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, 2023** **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.

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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, 2023** **December 31, 2024**, the Convertible Notes were recorded at the aggregate principal amount of **\$225.5 million** **\$225.5 million** less unamortized issuance costs of **\$2.8 million** **\$1.6 million** as a long-term liability on the consolidated balance sheets. As of **December 31, 2023** **December 31, 2024**, the fair value of the Convertible Notes was **\$330.1 million**, **\$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%** **3.1%**.

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

	Year Ended December 31,	
	2023	2022
Stated coupon interest	\$ 5,636	\$ 5,638
Amortization of debt issuance cost	1,121	1,094
Total interest expense	\$ 6,757	\$ 6,732

	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** **\$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** **\$10.47** per share and **\$15.80** **\$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.

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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**, **\$27.2 million**, as a reduction to additional paid-in capital within the consolidated statements of stockholders' equity.

## 11. Segment Reporting

### Long-Term Debt

## Long-Term Debt

On February 20, 2018, we entered into a \$175.0 million term Loan Agreement with CRG Servicing LLC. We borrowed \$100.0 million under the Loan Agreement at closing and the remaining \$75.0 million operate in March 2019 (collectively, "Term Loans"). Net proceeds under the Loan Agreement were \$173.3 million. The Term Loans under the Loan Agreement bore interest at a rate equal to 9.5% per annum. The Term Loans had a maturity date of December 31, 2023.

In May 2021, we repaid the principal one operating segment that is focused on the Term Loans, in full, using 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) <sup>(1)</sup> :			
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 <sup>(2)</sup>	(31,431)	(19,326)	(10,634)
Segment net income (loss) <sup>(3)</sup>	\$ 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 proceeds from 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 Convertible Notes issuance. In connection with the early repayment of the Term Loans, in the year ended December 31, 2021, we recorded \$5.2 million loss on debt extinguishment related to the amount we paid to terminate the Term Loans in excess of its carrying value at the time of the repayment. Our final payment of \$190.2 million to CRG Servicing LLC satisfied all face of our obligations under the Loan Agreement. With the full repayment consolidated statements of the Term Loans, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

We recorded \$7.0 million operations.

(3) Net income (loss) is our reported measure of interest expense related to the Term Loans during the year ended December 31, 2021.

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			Year Ended			Year Ended		
	December 31, 2023			December 31, 2022			December 31, 2021		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net									
HEPLISAV-B	\$ 213,295	\$ -	\$ 213,295	\$ 124,996	\$ 941	\$ 125,937	\$ 61,870	\$ -	\$ 61,870
CpG 1018 adjuvant	-	-	-	-	587,708	587,708	-	9	375,229
								375,22	
Total product revenue, net	\$ 213,295	\$ -	\$ 213,295	\$ 124,996	\$ 588,649	\$ 713,645	\$ 61,870	\$ 9	\$ 437,099
Other revenue	17,650	1,339	18,989	8,774	264	9,038	1,915	428	2,343
								375,65	
Total revenues	\$ 230,945	\$ 1,339	\$ 232,284	\$ 133,770	\$ 588,913	\$ 722,683	\$ 63,785	\$ 7	\$ 439,442

	Year Ended			Year Ended			Year Ended		
	December 31, 2024			December 31, 2023			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.

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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,		
	2023	2022	2021
Largest customer	28 %	21 %	21 %
Second largest customer	27 %	17 %	19 %
Third largest customer	17 %	16 %	19 %

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

	Year Ended		
	December 31,		
	2023	2022	2021
Largest collaboration partner	0 %	49 %	49 %
Second largest collaboration partner	0 %	35 %	24 %
Third largest collaboration partner	0 %	12 %	19 %

	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	Provisions	Credit or payments	Adjustments related to	Balance
	Beginning of	related to current	made during	prior periods	at End of
	Period	period sales	the period		Period
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
Year ended December 31, 2022:					

Accounts receivable reserves (1)	\$	3,823	\$	34,758	\$	(30,402)	\$	-	\$	8,179
Revenue reserve accruals (2)	\$	8,253	\$	24,806	\$	(22,507)	\$	-	\$	10,552

	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 (1)	Balance at End of Period	Balance at Beginning of Period	Additions	Subtractions	Reclassification (2)	Balance at End of Period
Year ended December 31, 2023:										
Year ended December 31, 2024:										
Contract asset, included in other current assets (2) (1)										
Contract asset, included in other current assets (2) (1)										
Contract asset, included in other current assets (2) (1)	\$ 71,965	\$ 17,650	\$ (16,919)	\$	(71,307)	\$ 1,389				
Contract asset, included in other assets (long term)	\$ -	\$ -	\$ -	\$	71,307	\$ 71,307				
Year ended December 31, 2022:										
Contract asset	\$ 62,525	\$ 17,556	\$ (8,116)	\$	-	\$ 71,965				
Year ended December 31, 2023:										
Contract asset, included in other current assets										
Contract asset, included in other current assets										
Contract asset, included in other current assets										
Contract asset, included in other assets (long term)										

(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.

(2) The \$1.4 million of contract asset is derived from our agreement with the DoD.

### 13. Net Income (Loss) Income Per Share

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

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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) **income** and diluted net income per share computations for our common stock are calculated as follows (in thousands):

	Year Ended		
	December 31,		
	2023	2022	2021
<b>Numerator</b>			
Net (loss) income	\$ (6,389)	\$ 293,156	\$ 76,713
Less: undistributed earnings allocated to participating securities		(283)	(4,569)
Net (loss) income allocable to common stockholders, basic	(6,389)	292,873	72,144
Add: undistributed earnings allocated to Series B and warrants	-	283	4,569
Less: undistributed earnings allocated to Series B and warrants	-	-	(4,190)
Add: interest expense on convertible notes	-	5,044	3,168
Less: removal of change in fair value of warrant liability	-	(1,801)	-
Net (loss) income allocable to common stockholders, diluted	\$ (6,389)	\$ 296,399	\$ 75,691
<b>Denominator</b>			
Weighted average shares used to compute net (loss) income allocable to common stockholders per share, basic	128,733	126,398	116,264
Effect of dilutive shares:			
Stock-based compensation plans	-	2,774	3,075
Convertible Notes (as converted to common stock)	-	21,543	13,667
Effect of dilutive warrants	-	82	-
Weighted average shares used to compute net (loss) income allocable to common stockholders per share, diluted	128,733	150,797	133,006

	Year Ended		
	December 31,		
	2024	2023	2022
<b>Numerator</b>			
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
<b>Denominator</b>			
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
<b>Net income (loss) per share attributable to common stockholders</b>			
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) **income** per share as the effect of their inclusion would have been anti-dilutive (in thousands).

	December 31,		
	2023	2022	2021
<b>Outstanding securities not included in diluted net (loss) income allocable to common stockholders per share calculation (in thousands):</b>			
Stock options and stock awards	15,158	7,165	5,953
Convertible Notes (as converted to common stock)	21,543	-	-
Warrants (as exercisable into common stock)	-	-	1,883

	December 31,		
	2024	2023	2022
<b>Outstanding securities not included in diluted net income (loss) allocable to common stockholders per share calculation (in thousands):</b>			
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 and Warrants Outstanding**

##### **Common Stock Outstanding**

As of **December 31, 2023** **December 31, 2024**, there were **129,530,228****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

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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****\$120.0 million** through Cowen as our sales agent. We agreed to pay Cowen a commission of up to **3%****3%** of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. As of **December 31, 2023** **December 31, 2024**, we had approximately **\$120.0 million****\$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****\$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~~ \$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~~ 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 2022, 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 ~~15,000,000~~ 11,400,000. The maximum number of shares of common stock that may be issued under the Amended 2018 EIP, will not exceed ~~32,600,000~~ 41,440,250 shares of common stock. As of ~~December 31, 2023~~ 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, 2023~~ December 31, 2024, there were ~~9,388,428~~ 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:

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### Stock Options

The following table summarizes the activity of stock options for the year ended ~~December 31, 2023~~ 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, 2022	9,339	\$ 10.70	4.61	\$ 16,291
Options granted	1,982	11.17		
Options exercised	(850)	7.48		
Options cancelled:				
Options forfeited (unvested)	(90)	10.93		
Options expired (vested)	(261)	21.39		
Balance at December 31, 2023	10,120	\$ 10.78	4.18	\$ 37,388
Vested and expected to vest at December 31, 2023	9,976	\$ 10.77	4.15	\$ 37,024
Exercisable at December 31, 2023	7,014	\$ 10.40	3.50	\$ 29,613

	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

The total fair value of stock options vested during the years ended December 31, 2023, December 31, 2024, 2023 and 2022 was \$17.5 million, \$19.5 million and 2021 was \$19.5 million, \$17.5 million and \$9.0 million, \$17.5 million, respectively.

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2022	3,479	\$ 11.00
Granted	2,748	11.48
Vested <sup>(1)</sup>	(1,515)	10.13
Forfeited	(267)	11.45
Non-vested as of December 31, 2023	4,445	\$ 11.57

	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 <sup>(1)</sup>	(1,940)	11.28
Forfeited	(438)	12.21
Non-vested as of December 31, 2024	5,363	\$ 12.11

Stock-based compensation expense related to RSUs was approximately \$20.4 million, \$13.2 million, \$28.7 million, \$20.4 million, and \$7.9 million, \$13.2 million for the years ended December 31, 2023, December 31, 2024, 2022, 2023, and 2021, 2022, respectively. The aggregate fair value of the RSUs outstanding as of December 31, 2023, December 31, 2024, 2022, 2023, and 2021, 2022, based on our stock price on that date, was \$62.2 million, \$37.0 million, \$68.5 million, \$62.2 million, and \$37.3 million, \$37.0 million, respectively.

[Table of Contents](#) 16.1 million, \$15.7 million and \$4.7 million, respectively.

### Market-based Performance Stock Units

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2022	193	\$ 11.62
		Number of Shares (in thousands)
Non-vested as of December 31, 2023		
Granted	364	18.25

Non-vested as of December 31, 2023	557	\$	15.95
Non-vested as of December 31, 2024			

Stock-based compensation expense related to PSUs was approximately \$2.5 million, \$0.8 million \$5.7 million, \$2.5 million, and \$1.8 million \$0.8 million for the years ended December 31, 2023 December 31, 2024, 2022 2023, and 2021, 2022, respectively. The aggregate intrinsic value of the PSUs outstanding as of December 31, 2023 December 31, 2024, 2022 2023 and 2021, 2022, based on our stock price on that date, was \$7.8 million, \$2.1 million \$14.2 million, \$7.8 million, and \$3.3 million, \$2.1 million, respectively.

Performance-based Options

As of December 31, 2023 December 31, 2024, approximately 36,000 shares underlying performance-based options were outstanding.

Significant Assumptions in Estimating Option Fair Value

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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			Market-Based Performance Stock Units			Employee Stock Purchase Plan		
	Year Ended December 31,			Year Ended December 31,			Year Ended December 31,		
	2023	2022	2021	2023	2022	2021	2023	2022	2021
Weighted-average fair value	\$ 7.32	\$ 7.95	\$ 7.17	\$ 18.25	\$ 11.62	\$ 8.40	\$ 5.35	\$ 7.37	\$ 6.48
Risk-free interest rate	4.0 %	2.0 %	0.7 %	4.3 %	1.7 %	1.92 %	4.9 %	2.1 %	0.1 %
Expected life (in years)	4.5	4.5	4.5	2.9	2.9	2.9	1.3	1.3	1.2
Expected volatility	0.8	0.8	0.9	0.9	0.9	0.9	0.7	1.0	1.0

From 0.03% to

Risk-free interest rate

Expected life (in years)

4.2 %

4.0 %

2.0 %

4.3 %

4.3 %

1.7 %

4.7

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

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.

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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,		
	2023	2022	2021
Employees and directors stock-based compensation expense	\$ 42,592	\$ 32,915	\$ 21,285
	Year Ended December 31,		
	2023	2022	2021
Research and development	\$ 9,285	\$ 5,954	\$ 3,818
Selling, general and administrative	29,069	23,118	14,894
Cost of sales - product	1,839	1,123	553
Inventories	2,399	2,720	2,020
Total	\$ 42,592	\$ 32,915	\$ 21,285

	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, 2023** **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 **\$46.1 million**, **\$50.0 million**, which is expected to be recognized over the remaining weighted-average vesting period of **1.61.7** years. As of **December 31, 2023** **December 31, 2024**, the total unrecognized compensation cost related to PSUs amounted to **\$5.5 million**.

**\$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**, **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.

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The purchase price per share is the lesser of (i) **85% 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% 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, 2023** **December 31, 2024**, employees have acquired approximately **161,000** **184,000** shares of our common stock under the Employee Stock Purchase Plan and approximately **722,000** **538,000** shares of our common stock remained available for future purchases under the Employee Stock Purchase Plan.

As of **December 31, 2023** **December 31, 2024**, the total unrecognized compensation cost related to shares of our common stock under the Employee Stock Purchase Plan amounted to **\$1.0 million**, **\$0.4 million**, which is expected to be recognized over the remaining weighted-average vesting period of **1.21.4** 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 \$1.3 million, \$0.9 million \$1.8 million, \$1.3 million and \$0.3 million \$0.9 million for the years ended December 31, 2023 December 31, 2024, 2023 and 2022, and 2021, respectively.

## 17. Income Taxes

Consolidated income (loss) income 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

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	Year Ended December 31,		
	2023	2022	2021
U.S.	\$ (6,275)	\$ 292,460	\$ 75,954
Non U.S.	1,908	1,839	1,567
Total	\$ (4,367)	\$ 294,299	\$ 77,521

The components of the consolidated income tax provision for the years ended December 31, 2023 December 31, 2024, 2022 2023 and 2021 2022 were as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022	Year Ended December 31, 2021
<b>Current</b>			
Federal	\$ (178)	\$ (165)	\$ 345
State	1,533	897	260
Non-US	667	411	203
Total current tax expense	2,022	1,143	808
<b>Deferred</b>			
Federal	-	-	-
State	-	-	-
Non-US	-	-	-
Total deferred tax expense	-	-	-
<b>Total income tax expense</b>	<b>\$ 2,022</b>	<b>\$ 1,143</b>	<b>\$ 808</b>

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	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
<b>Current</b>			
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
<b>Deferred</b>			
Federal	-	-	-
State	-	-	-
Non-US	-	-	-
Total deferred tax expense	-	-	-
<b>Total income tax expense</b>	<b>\$ 3,546</b>	<b>\$ 2,022</b>	<b>\$ 1,143</b>

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, 2023**, **December 31, 2024**, **2022** and **2021** were as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Income tax provision (benefit) at federal statutory rate	\$ (917)	\$ 61,775	\$ 16,397
State tax	574	(2,942)	3,576
Business credits	(2,050)	(3,246)	(982)
Uncertain tax positions	334	586	424
Deferred compensation charges	830	(473)	131
Change in valuation allowance	1,466	(324)	(86,847)
Section 162(m) limitation	1,963	1,779	1,241
Mark-to-market of warrants	-	(378)	10,364
Net operating loss and tax credit limitation	-	(56,908)	56,459
Other <sup>(1)</sup>	(518)	879	(290)
Foreign taxes	340	395	335
Total income tax expense	\$ 2,022	\$ 1,143	\$ 808

	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 <sup>(1)</sup>	(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, and 2021, Foreign taxes were included in Other.

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

	December 31,	
	2023	2022
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 96,336	\$ 113,228
Research credit carryforwards	34,940	33,444
Section 174 capitalization	22,556	15,308
Lease liability	8,868	9,530
Stock compensation	10,572	7,780
Accruals and reserves	15,808	9,089
Other	348	337
Total deferred tax assets	189,428	188,716
Less valuation allowance	(180,387)	(178,920)
Net deferred tax assets	9,041	9,796

<b>Deferred tax liabilities:</b>		
Fixed assets	(2,667)	(2,916)
Operating lease right-of-use assets	(6,345)	(6,785)
Other	(29)	(95)
Total deferred tax liabilities	(9,041)	(9,796)
Net deferred tax assets	\$ -	\$ -

	December 31,	
	2024	2023
<b>Deferred tax assets:</b>		
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
<b>Deferred tax liabilities:</b>		
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, 2023** **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.

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The valuation allowance **increased** **decreased** by **\$1.5 million** **\$7.9 million** during the year ended **December 31, 2023** **December 31, 2024** and **decreased** **increased** by **\$0.3 million** **\$1.5 million** during the year ended **December 31, 2022** **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** **offset** by utilization of net operating losses. The decrease in valuation allowance during the year ended December 31, 2022 was due to a decrease in our deferred tax assets, predominantly related to utilization of net operating losses, offset by updates to the Section 382 analysis.

As of **December 31, 2023** **December 31, 2024**, we had federal net operating loss carryforwards of approximately **\$23.1 million**, **\$0.4 million**, which began to expire in the year **2024**, **2025**, federal net operating loss carryforwards of approximately **\$353.5 million**, **\$293.1 million**, which do not expire and federal research and development tax credits of approximately **\$28.3 million**, **\$26.5 million**, which expire in the years **2024** **2025** through **2043**.

2044.

As of **December 31, 2023** **December 31, 2024**, we had net operating loss carryforwards for California and other states for income tax purposes of approximately **\$283.9 million**, **\$262.9 million**, which expire in the years **2024** **2025** through **2040**, **2041**, and California state research and development tax credits of approximately **\$22.3 million**, **\$21.8 million**, which do not expire.

As of **December 31, 2023** **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 \$12.1 million \$12.4 million and \$11.3 million \$12.1 million as of December 31, 2023 December 31, 2024 and 2022, 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,	
	2023	2022
Balance at beginning of year	\$ (11,339)	\$ (5,615)
Tax positions related to the current year		
Additions	(762)	(670)
Reductions	-	-
Tax positions related to the prior year		
Additions	-	(5,054)
Reductions	-	-
Settlements	-	-
Lapses in statute	-	-
Balance at end of year	\$ (12,101)	\$ (11,339)

	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, 2023 December 31, 2024, there was were no interest and no material penalties recognized in the provision for income taxes. As of December 31, 2022 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, 2023 December 31, 2024.

We are subject to income tax examinations for U.S. federal and state income taxes from 2002 2001 forward. We are subject to tax examination in Germany from 2018 2020 forward, in India from 2019 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, 2023** **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.

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## Report of Independent Registered Public Accounting Firm

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

### Opinion on Internal Control **over Over** Financial Reporting

We have audited Dynavax Technologies Corporation's internal control over financial reporting as of **December 31, 2023** **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, 2023** **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, 2023** **December 31, 2024** and **2022, and 2023**, the related consolidated statements of operations, comprehensive **income (loss) income**, stockholders' equity and cash flows for each of the three years in the period ended **December 31, 2023** **December 31, 2024** and the related notes **of the Company** and our report dated **February 22, 2024** **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 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 22, 2024 20, 2025

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(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

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None.

\$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.

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### 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 2024 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, 2023 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](http://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.

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### 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) Income

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

##### 2. Financial Statement Schedules

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

##### (b) Exhibits

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

3.6	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	June 2, 2017	001-34207	
3.7	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	July 31, 2017	001-34207	
3.8	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	May 29, 2020	001-34207	

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3.2	<a href="#">Certificate of Amendment of Amended and Restated Certificate of Incorporation</a>	3.1	8-K	January 4, 2010	001-34207	
3.3	<a href="#">Certificate of Amendment of Amended and Restated Certificate of Incorporation</a>	3.1	8-K	January 5, 2011	001-34207	
3.4	<a href="#">Certificate of Amendment of Amended and Restated Certificate of Incorporation</a>	3.6	8-K	May 30, 2013	001-34207	
3.5	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	November 10, 2014	001-34207	
3.6	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	June 2, 2017	001-34207	
3.7	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	July 31, 2017	001-34207	
3.8	<a href="#">Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation</a>	3.1	8-K	May 29, 2020	001-34207	
3.9	<a href="#">Amended and Restated Bylaws</a>	3.8	10-Q	November 6, 2018	001-34207	

3.9	<a href="#">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</a>	3.1	8-K	October 29, 2024	001-34207	
3.10	<a href="#">Amended and Restated Bylaws</a>	3.8	10-Q	November 6, 2018	001-34207	

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4.1	<a href="#">Description of Capital Stock</a>					X
4.2	<a href="#">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</a>					
4.3	<a href="#">Form of Specimen Common Stock Certificate</a>	4.2	S-1/A	January 16, 2004	333-109965	
4.4	<a href="#">Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021</a>	4.1	8-K	May 13, 2021	001-34207	
4.5	<a href="#">Form of Global Note, representing Dynavax Technologies Corporation's 2.5% Convertible Senior Notes due 2026</a>	4.2	8-K	May 13, 2021	001-34207	

4.6	<a href="#">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</a>	4.1	8-K	October 29, 2024	001-34207	
4.7	<a href="#">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</a>	4.1	8-K	December 27, 2024	001-34207	
10.1+	<a href="#">Employment Agreement, dated July 12, 2013, by and between Robert Janssen, M.D. and Company</a>	10.85	10-K	March 10, 2014	001-34207	
10.2+	<a href="#">Chief Executive Officer Letter, dated December 13, 2019, between Company and Ryan Spencer</a>	10.17	10-K	March 11, 2020	001-34207	
10.3+	<a href="#">President and Chief Operating Officer Letter, dated December 13, 2019, between Company and David Novack</a>	10.18	10-K	March 11, 2020	001-34207	
10.4+	<a href="#">Offer Letter, dated December 14, 2020, by and between Company and Kelly MacDonald</a>	10.33	10-K	February 25, 2021	001-34207	
10.5+	<a href="#">Offer Letter, dated May 26, 2021, by and between Company and John Sebir</a>					X
10.6+	<a href="#">Consulting Agreement, effective January 16, 2023, between Company and Peter Paradiso</a>	10.1	10-Q	May 2, 2023	001-34207	

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4.1	<a href="#">Description of Capital Stock</a>	4.1	10-K	February 28, 2022	001-34207	
4.2	Reference is made to Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> , <a href="#">3.4</a> , <a href="#">3.5</a> , <a href="#">3.6</a> , <a href="#">3.7</a> , <a href="#">3.8</a> and <a href="#">3.9</a> above					
4.3	<a href="#">Form of Specimen Common Stock Certificate</a>	4.2	S-1/A	January 16, 2004	333-109965	
4.4	<a href="#">Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021</a>	4.1	8-K	May 13, 2021	001-34207	
4.5	<a href="#">Form of Global Note, representing Dynavax Technologies Corporation's 2.5% Convertible Senior Notes due 2026</a>	4.2	8-K	May 13, 2021	001-34207	
10.1+	<a href="#">Employment Agreement, dated July 12, 2013, by and between Robert Janssen, M.D. and Company</a>	10.85	10-K	March 10, 2014	001-34207	
10.2+	<a href="#">Chief Executive Officer Letter, dated December 13, 2019, between Company and Ryan Spencer</a>	10.17	10-K	March 11, 2020	001-34207	
10.3+	<a href="#">President and Chief Operating Officer Letter, dated December 13, 2019, between Company and David Novack</a>	10.18	10-K	March 11, 2020	001-34207	
10.4+	<a href="#">Offer Letter, dated December 14, 2020, by and between Company and Kelly MacDonald</a>	10.33	10-K	February 25, 2021	001-34207	

10.5+	<a href="#">Consulting Agreement, effective January 16, 2023, between Company and Peter Paradiso</a>	10.1	10-Q	May 2, 2023	001-34207	
10.6+	<a href="#">Form of Indemnification Agreement</a>	10.1	10-Q	November 7, 2019	001-34207	
10.7+	<a href="#">Form of Management Continuity and Severance Agreement between Company and certain of its executive officers</a>	10.3	10-Q	August 3, 2023	001-34207	
10.8+	<a href="#">Dynavax Technologies Corporation U.S. Annual Bonus Plan</a>	10.23	10-K	March 11, 2020	001-34207	
10.9+	<a href="#">Non-Employee Director Compensation Policy</a>	10.34	10-K	February 28, 2022	001-34207	

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

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10.10	<a href="#">Sales Agreement, dated August 6, 2020, between Company and Cowen and Company, LLC</a>	10.3	10-Q	August 6, 2020	001-34207	
10.11	<a href="#">Form of Confirmation for Capped Call Transactions</a>	10.1	8-K	May 13, 2021	001-34207	
10.12+	<a href="#">Dynavax Technologies Corporation Amended and Restated 2014 Employee Stock Purchase Plan</a>	Appendix A	DEF 14A	April 16, 2021	001-34207	
10.13+	<a href="#">Amended and Restated Dynavax Technologies Corporation 2018 Equity Incentive Plan</a>	Appendix A	DEF 14A	April 14, 2022	001-34207	
10.14+	<a href="#">Form of Option Grant Notice and Option Agreement under the 2018 Equity Incentive Plan</a>	10.3	8-K	June 1, 2018	001-34207	
10.15+	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan</a>	10.2	8-K	June 1, 2018	001-34207	
10.16+	<a href="#">Restricted Stock Unit Award Agreement for Directors under the 2018 Equity Incentive Plan</a>	10.11	10-K	February 28, 2022	001-34207	
10.17+	<a href="#">Amended and Restated Dynavax Technologies Corporation 2021 Inducement Award Plan</a>	10.3	10-Q	August 4, 2021	001-34207	
10.18	<a href="#">Office/Laboratory Lease, dated September 17, 2018, between Company and Emery Station West, LLC</a>	10.1	10-Q	November 6, 2018	001-34207	
10.19	<a href="#">Sublease, dated July 12, 2019, by and between Company and Zymergen Inc.</a>	10.3	10-Q	November 7, 2019	001-34207	
10.20	<a href="#">Commercial Lease Agreement, dated September 13, 2021, by and between Onyx Düsseldorf S.à.r.l. and Dynavax GmbH</a>	10.2	10-Q	November 4, 2021	001-34207	
10.21	<a href="#">Lease Agreement, dated March 15, 2022, by and between Company and SPUS8 2100 Powell, L.P.</a>	10.1	10-Q	May 5, 2022	001-34207	
10.22+	<a href="#">Commercial Manufacturing and Supply Agreement, dated November 22, 2013, between Company and Baxter Pharmaceutical Solutions LLC</a>	10.33	10-K	March 8, 2018	001-34207	
10.23^	<a href="#">First Amendment to Commercial Manufacturing and</a>	10.3	10-Q	November 4, 2021	001-34207	

10.23 •	<a href="#">English Translation of Commercial Lease Agreement, dated September 13, 2021, by and between Onyx Düsseldorf S.à r.l. and Dynavax GmbH</a>	10.2	10-Q	November 4, 2021	001-34207	
10.24•	<a href="#">English Translation of Addendum to Commercial Lease Agreement, dated January 4, 2024, by and between Onyx Düsseldorf S.à r.l. and Dynavax GmbH</a>					X
10.25•	<a href="#">Lease Agreement, dated March 15, 2022, by and between Company and SPUS8 2100 Powell, L.P.</a>	10.1	10-Q	May 5, 2022	001-34207	
10.26•	<a href="#">First Amendment to Lease, dated December 2, 2024, by and between Company and SPUS8 2100 Powell, L.P.</a>					X
10.27†	<a href="#">Commercial Manufacturing and Supply Agreement, dated November 22, 2013, between Company and Baxter Pharmaceutical Solutions LLC</a>	10.33	10-K	March 8, 2018	001-34207	
10.28^	<a href="#">First Amendment to Commercial Manufacturing and Supply Agreement, dated September 10, 2021, by and between Company and Baxter Pharmaceutical Solutions LLC</a>	10.3	10-Q	November 4, 2021	001-34207	
10.24† 10.29^	<a href="#">Second Amendment to Commercial Manufacturing and Supply Agreement, dated July 27, 2016 as of January 16, 2025, by and between Company and Baxter Pharmaceutical Solutions LLC d/b/a Simtra Biopharma Solutions</a>					X
10.30^	<a href="#">Supply Agreement, dated February 10, 2025, between Company and West Pharmaceutical Services, Inc.</a>	10.36	10-K	March 8, 2018	001-34207	X
10.25^ 10.31^	<a href="#">Agreement, dated January 29, 2021 between Company and Coalition for Epidemic Preparedness Innovations</a>	10.31	10-K	February 25, 2021	001-34207	
10.26^ 10.32^	<a href="#">First Amendment to Agreement, dated May 3, 2021, by and between Company and Coalition for Epidemic Preparedness Innovations</a>	10.1	10-Q	August 4, 2021	001-34207	

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10.27^ 10.33^	<a href="#">Waiver and Second Amendment to Agreement, dated effective as of April 27, 2023, by and between Company and Coalition for Epidemic Preparedness Innovations</a>	10.2	10-Q	August 3, 2023	001-34207	
10.28^ 10.34^	<a href="#">Supply Agreement, dated effective April 1, 2021, between Company and Becton, Dickinson and Company</a>	10.35	10-K	February 23, 2023	001-34207	
10.29^ 10.35^	<a href="#">Amendment #1 to Supply Agreement, dated September 28, 2022, between Company and Becton, Dickinson and Company</a>	10.36	10-K	February 23, 2023	001-34207	
10.30^ 10.36^	<a href="#">Supply Agreement, dated June 29, 2021, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc., and Clover Biopharmaceuticals (Hong Kong) Co., Limited</a>	10.6	10-Q	August 4, 2021	001-34207	
10.31^ 10.37^	<a href="#">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.</a>	10.2	10-Q	November 3, 2022	001-34207	
10.32^ 10.38^	<a href="#">Letter Agreement No. 2, dated October 31, 2022, by and among Company, Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited</a>	10.4	10-Q	November 3, 2022	001-34207	

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10.33^ 10.39^	<a href="#">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</a>	10.37	10-K	February 23, 2023	001-34207	
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<a href="#">10.34^</a> <a href="#">10.40^</a>	<a href="#">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</a>	10.38	10-K	February 23, 2023	001-34207	
<a href="#">10.35^</a> <a href="#">10.41^</a>	<a href="#">Supply Agreement, dated July 1, 2021, by and between Company and Biological E. Limited</a>	10.7	10-Q	August 4, 2021	001-34207	
<a href="#">10.36^</a> <a href="#">10.42^</a>	<a href="#">Amendment No. 1 to Supply Agreement, dated effective as of June 23, 2022, by and between Company and Biological E. Limited</a>	10.1	10-Q	November 3, 2022	001-34207	
<a href="#">10.37^</a>						

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10.43^	<a href="#">Amendment No. 2 to Supply Agreement, dated effective as of September 30, 2022, by and between Company and Biological E. Limited</a>	10.3	10-Q	November 3, 2022	001-34207	
10.38^ 10.44^	<a href="#">Amendment No. 3 to Supply Agreement, dated effective as of April 26, 2023, by and between Company and Biological E. Limited</a>	10.1	10-Q	August 3, 2023	001-34207	
10.39^ 10.45^	<a href="#">Supply Agreement, effective as of September 7, 2023, by and between Company and Nitto Denko AVECIA Inc.</a>	10.1	10-Q	November 2, 2023	001-34207	
19.1	<a href="#">Insider Trading Policy</a>					X
21.1	<a href="#">List of Subsidiaries</a>					X
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>					X
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					X
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					X

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32.1*	<a href="#">Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
32.2*	<a href="#">Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X

97.1+	<a href="#">Dynavax Technologies Corporation Incentive Compensation Recoupment Policy</a>	97.1	10-K	February 22, 2024	001-34207	✖
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EX—101.INS	<div>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.</div>
EX—101.SCH	<div>Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document</div>
EX—104	<div>The cover page for this Annual Report on Form 10-K has been formatted in Inline XBRL</div>

† We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

+ Indicates management contract, compensatory plan or arrangement.

^ **Certain** 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.

None.

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SIGNATURES

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 T

By: \_\_\_\_\_

Dynavax Technologies Corporation ECHNOLOGIES CORPORATION

/s/ RYAN SPENCER

Ryan Spencer

Chief Executive Officer and Director

(Principal Executive Officer)

Date: February 22, 2024  
February 20, 2025

By: \_\_\_\_\_

/s/ KELLY MACDONALD

Kelly MacDonald

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

Date: February 22, 2024 February 20, 2025

Signature

By: Title

Date

/s/ JUSTIN  
BURGESS

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Date: February 22, 2024

Signature	Title	Date
/s/ RYAN SPENCE R  Ryan Spencer	Chief Executive Officer and Director  (Principal Executive Officer)	February 22, 2024 20, 2025
/s/ KELLY MACDONALD  Kelly MacDonald	Chief Financial Officer  (Principal Financial Officer)	February 22, 2024 20, 2025
/s/ JUSTIN BURGES S  Justin Burgess	Controller, Chief Accountin g Officer ( and Principal Accountin g Officer)	February 22, 2024
/s/ SCOTT MYERS  Scott Myers	Chairman of the Board	February 22, 2024 20, 2025

<div>/s/ FRANCIS R. CANO</div> <div>Francis R. Cano, Ph.D.</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ JULIE EASTLAND</div> <div>Julie Eastland</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ EMILIO EMINI</div> <div>Emilio Emini, Ph.D.</div>	Director		February 20, 2025
<div>/s/ DANIEL L. KISNER</div> <div>Daniel L. Kisner, M.D.</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ BRENT MACGREGOR</div> <div>Brent MacGregor</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ PETER R. PARADISO</div> <div>Peter R. Paradiso</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ PEGGY V. PHILLIPS</div> <div>Peggy V. Phillips</div>	Director	Director	February 22, 2024
			20, 2025
<div>/s/ LAUREN SILVERNAIL</div> <div>Lauren Silvernail</div>	Director		February 20, 2025
<div>/s/ ELAINE D. SUN</div> <div>Elaine D. Sun</div>	Director	Director	February 22, 2024
			20, 2025

	Exhibit 4.1
DESCRIPTION OF CAPITAL STOCK	
References herein to “Dynavax,” “our,” “we,” “us” and the “Company” refer only to Dynavax Technologies Corporation.	
General	
Our authorized capital stock consists of 278,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share, 300,000 of which has been designated Series A Junior Participating Preferred Stock, par value \$0.001 per share, or Preferred Shares. Our common stock and associated preferred	

shares purchase rights, or Rights, are the only securities of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

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

## **Common Stock**

### ***Voting Rights***

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

### ***Dividends***

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

### ***Liquidation***

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

### ***Rights and Preferences***

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

## **Preferred Stock**

### ***General***

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

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

### ***Certificate of Incorporation and Bylaws***

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

repeal or modification of certain provisions of our certificate of incorporation relating to, among other things, the classification of our board of directors and filling of vacancies on our board of directors. Our certificate of incorporation and bylaws also require a 66-2/3% stockholder vote for the stockholders to adopt, amend or repeal certain provisions of our bylaws relating to stockholder proposals at annual meetings, director nominees and the number and term of office of directors. Our board of directors also has the unilateral authority to repeal, alter or amend our bylaws or adopt new bylaws by unanimous written consent or at a meeting by the affirmative vote of a majority of the directors.

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

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

#### **Section 203 of Delaware Law**

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

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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

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

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

#### **Choice of Forum**

Our bylaws provide that, unless we consent to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply,

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enforce, or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

#### **Stockholder Rights Agreement**

On October 28, 2024, our board of directors, or the Board, declared a dividend of one preferred share purchase right, or Right, to purchase one-thousandth of one share of our newly designated Preferred Shares for each outstanding share of common stock to the stockholders of record as of the close of business on November 8, 2024, or the Record Date, and adopted a limited duration stockholder rights plan, or the Rights Plan, effective immediately, as set forth in the Rights Agreement, dated as of October 28, 2024, or the Rights Agreement, by and between the Company and Computershare Trust Company, N.A., as Rights Agent (as defined therein).

The following is a summary description of the Rights and material terms and conditions of the Rights Agreement.

#### **The Rights**

Pursuant to the terms of the Rights Agreement, the Rights will not be exercisable and will trade with shares of our common stock until the earlier to occur of (a) the tenth (10<sup>th</sup>) calendar day (or such later date as may be determined by the Board) after a person or group acquires beneficial ownership of 15% (18% in the case of a passive institutional investor) or more of outstanding common stock, or an Acquiring Person, or, in the event that the Board determines on or before such tenth (10<sup>th</sup>) calendar day to effect an exchange and determines in that a later date is advisable, such later date that is not more than twenty (20) calendar days after the date such shares of our common stock are acquired, or (b) the tenth (10<sup>th</sup>) business day (or such later date as may be determined by action of the Board prior to such time as any person or entity becomes an Acquiring Person) following the date of commencement, or the first announcement, of an intention to commence, a tender offer or exchange offer, the consummation of which would result in any person or entity, or group of persons or entities acting in concert, becoming an Acquiring Person. The term "Acquiring Person" is subject to certain customary exceptions whereby certain stockholders that would have otherwise been an Acquiring Person are excluded from the definition of "Acquiring Person." Any stockholders with beneficial ownership of our common stock above the applicable threshold as of the first public announcement of the Rights Plan on October 29, 2024 are grandfathered at their current ownership levels but are not permitted to increase their ownership without triggering the Rights. Prior to exercise, the Rights do not give their holder any dividend, voting or liquidation rights.

The date when the Rights separate from our common stock and become exercisable is referred to herein as the "Distribution Date." Unless and until the occurrence of such date, common stock certificates or, in the case of uncertificated shares, notations in the book-entry account system, will evidence the Rights, and any transfer of shares of common stock will constitute a transfer of the related Rights. After the Distribution Date, the Rights will be evidenced by separate book-entry credits or by Rights certificates that we will mail to all eligible, certificated holders of our common stock. Any Rights held by an Acquiring Person will be null and void and may not be exercised.

#### **Exercise Price**

Pursuant to the terms of the Rights Agreement, after the Distribution Date, each Right will entitle the holder thereof to purchase one-thousandth (1/1,000th) of a Preferred Share for \$52.00, subject to adjustment, or the Exercise Price. Each one-thousandth (1/1,000th) of a Preferred Share has economic terms similar to that of one share of our common stock. The Exercise Price payable, and the number of Preferred Shares or other securities or other property issuable upon exercise of the Rights, will be subject to adjustment from time to time to prevent dilution in the event

of a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Shares. The exercise of Rights to purchase Preferred Shares will at all times be subject to the availability of a sufficient number of authorized but unissued Preferred Shares. Notwithstanding the foregoing, with certain exceptions, no adjustment in the Exercise Price will be required until cumulative adjustments require an adjustment of at least 1% in such Exercise Price. No fractional Preferred Shares will be issued (other than fractions which are integral multiples of the number of one one-thousandth (1/1,000th) of a Preferred Share issuable upon the exercise of one Right, which may, at the Company's election, be evidenced by depositary receipts), and in lieu thereof, an adjustment in cash will be made based on the market price of the Preferred Shares on the last trading day prior to the date of exercise.

### **Beneficial Ownership**

Pursuant to the terms of the Rights Agreement, certain synthetic interests in securities created by derivative positions — whether or not such interests are considered to be ownership of underlying shares of our common stock or are reportable for purposes of Regulation 13D of the Securities Exchange Act of 1934, as amended — are treated as beneficial ownership of the number of shares of common stock equivalent to the economic exposure created by the derivative position, to the extent actual shares of common stock are directly or indirectly held by counterparties to the derivatives contracts. Swaps dealers unassociated with any control intent or intent to evade the purposes of the Rights Agreement are excepted from such imputed beneficial ownership. In addition, shares held by affiliates and associates of an Acquiring Person, including shares that are subject of, or the reference securities for, or that underly, any derivative position of such persons, will be deemed to be beneficially owned by the Acquiring Person. In addition, any securities beneficially owned by a third party with whom the Acquiring Person has any agreement, arrangement or understanding (whether or not in writing) (i) for the purpose of acquiring, holding or voting securities of the Company or (ii) to cooperate in obtaining, changing or influencing control of the Company, will be deemed to be beneficially owned by the Acquiring Person.

### **Consequences of a Person or Group Becoming an Acquiring Person**

- **Flip-In.** If a person or group becomes an Acquiring Person, all holders of Rights except the Acquiring Person or its affiliates may, for the Exercise Price, purchase shares of our common stock with a market value of twice the Exercise Price.
- **Exchange.** In lieu of the "flip-in" feature described above, the Board may, at its option at any time after a person or group becomes an Acquiring Person, exchange the Rights (other than Rights owned by the Acquiring Person or its affiliates), in whole or in part, for shares of our common stock at an exchange ratio of one share of common stock per Right (subject to adjustment).
- **Flip-Over.** If the Company is later acquired in a merger or similar transaction after the Distribution Date, all holders of Rights except the Acquiring Person or its affiliates may purchase, for the Exercise Price, a number of shares of the common stock of the Principal Party (as defined in the Rights Agreement) having a market value of twice the Exercise Price.

### **Company Preferred Share Provisions**

Each Preferred Share, if issued:

- will not be redeemable;
- when, as and if any dividend is declared on our common stock, entitle the holder to quarterly dividend payments in an amount per share equal to 1,000 times the aggregate per share amount of all cash dividends, and 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than a dividend payable in common stock or a subdivision of the outstanding common stock (by reclassification or otherwise), declared on common stock since the immediately preceding quarterly dividend payment date or, with respect to the first date when quarterly dividends are payable in

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cash, since the first issuance of any share or fraction of a share of Series A Junior Participating Preferred Stock;

- will entitle the holder upon liquidation either to receive a preferential liquidation payment of the greater of (a) \$1,000 per Preferred Share, plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment and (b) an aggregate amount per Preferred Share equal to 1,000 times the aggregate amount to be distributed per share to holders of our common stock plus an amount equal to any accrued and unpaid dividends on such Preferred Shares;
- will have the same voting power as 1,000 shares of our common stock;
- if shares of our common stock are exchanged via merger, consolidation, or a similar transaction, will entitle the holder to a per share payment equal to the payment made on 1,000 shares of our common stock; and

- will rank junior to any other series of the Company's preferred stock in the event such other preferred stock is issued by the Company, unless the terms of any such series provide otherwise.

The value of one one-thousandth (1/1,000th) interest in a Preferred Share is intended to approximate the value of one share of our common stock.

#### **Expiration**

The Rights will expire on the earlier of (i) the one year anniversary of the date of the Rights Agreement and (ii) the day following the certification of the voting results of the Company's 2025 annual meeting of stockholders, or any postponement or adjournment thereof, if at or prior to such annual meeting or adjournment thereof, the Company's stockholders do not duly pass a proposal approving the Rights Agreement, such earlier date, the Final Expiration Date, unless the Rights are earlier redeemed or exchanged by the Company.

#### **Redemption**

The Board may redeem the Rights for \$0.001 per Right at any time prior to the earlier of (A) such time as any person or group becomes an Acquiring Person or (B) the close of business on the Final Expiration Date. Following the expiration of the above periods, the Rights become nonredeemable. If the Board redeems any Rights, it must redeem all of the Rights. Once the Rights are redeemed, the only right of the holders of Rights pursuant to the Rights Agreement will be to receive the redemption price of \$0.001 per Right. The redemption price will be adjusted if the Company effects a stock split or stock dividend of our common stock.

#### **Anti-Dilution Provisions**

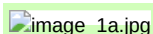
Rights will have the benefit of certain anti-dilution provisions set forth in the Rights Agreement.

#### **Amendments**

The terms of the Rights Agreement may be amended by the Board without the consent of the holders of the Rights. After a person or group becomes an Acquiring Person, the Board may not amend the Rights Agreement in a way that adversely affects holders of the Rights.

#### **Miscellaneous**

The Rights Agreement does not contain any dead-hand, slow-hand, no-hand or similar feature that limits the ability of a future Board to redeem the Rights. Until a Right is exercised, it does not entitle the holder thereof to any additional rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.



## **Exhibit 10.5**

May 26, 2021

John Slebir  
[address]

Subject: Revised Offer Letter

Dear John:

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

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

#### **COMPENSATION & BENEFITS**

Your compensation will be \$37,500.00 per month, annualized to \$450,000.00, less payroll deductions and all required withholdings. You will be paid semi-monthly on the 15<sup>th</sup> of each month and on the last day of each month. You will be eligible to participate in the Company's standard benefit programs

including medical, dental, and vision insurance programs for yourself and your qualified dependents beginning on your first day of employment. There will be an employee contribution for these coverages. Dynavax offers up to 13 company paid holidays per year, life insurance, disability insurance, long-term care insurance, Flexible Spending Account, 401(k) match, and Employee Stock Purchase Plan. The Company may modify compensation and benefits from time to time as it deems necessary.

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

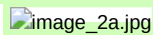
#### **BONUS**

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

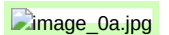
#### **STOCK OPTIONS**

Specifically, with respect to the stock option grant, as a material inducement to you entering into employment with Dynavax Technologies Corporation (the "Company"), we propose granting you a stock option to purchase 300,000 shares of the Company's common stock, subject to approval by the Compensation Committee of the Company's Board of Directors. This stock option would be a non-qual, and would have an exercise price equal to the fair market value of the Company's common stock on the date of

[2100 Powell Street, Suite 900, Emeryville, California 94608](#)



[Phone: 510-848-5100 Toll-Free: 877-848-5100 Fax: 510-848-1327 www.dynavax.com](#)



grant and would be subject to all of the terms and conditions set forth in the applicable award agreement and applicable stock incentive plan. This stock option would vest over three years as follows: 1/3 of the shares subject to the stock option would vest on the first anniversary of the date you commence employment with the Company, and 1/36 of the shares subject to the stock option would vest on the last day of each month thereafter, provided that vesting would cease upon termination of your continuous service with the Company and/or its affiliates.

#### **SIGN-ON BONUS**

You will receive a \$100,000.00 sign-on bonus, less applicable withholding deductions that will be paid in the pay cycle after completing 60-days of full-time employment. If you voluntarily terminate your employment within 12-months of your start date, this amount must be reimbursed to the Company.

#### **OTHER AGREEMENTS**

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

#### **EMPLOYMENT VERIFICATION & BACKGROUND CHECK**

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

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

#### **COMPANY POLICY & PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT**

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

#### **WORKING HOURS**

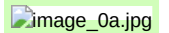
Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt salaried employee, you will be expected to work additional hours as required by the nature of your work assignments.

#### **AT-WILL EMPLOYMENT**

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

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

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image\_0a.jpg

Please sign and date this letter and return it via DocuSign to Human Resources by **Tuesday, June 1, 2021**, if you wish to accept employment with Dynavax under the terms described above. If you accept our offer, we will work with you to find a mutually agreeable start date.

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

Sincerely,

/s/ Ryan Spencer

Ryan Spencer  
CEO

**Accepted:**

/s/ John Slebir 5/27/2021  
John Slebir      Date

3

**EXHIBIT 10.7**

#### **AMENDMENT NO. 1 TO CONSULTING AGREEMENT AND STATEMENT OF WORK NO. 1**

This Amendment No. 1, effective as of January 16, 2025 (the "**Amendment No. 1 Effective Date**") ("**Amendment No. 1**") amends that certain Consulting Agreement and Statement of Work No. 1 having an effective date of January 16, 2023 by and between the parties hereto (each a "**Party**" and collectively the "**Parties**") (the "**Agreement**").

WHEREAS, the Parties now wish to amend the Agreement as set forth below:

NOW, THEREFORE, in exchange for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Section 11a. is hereby deleted in its entirety and replaced with the following:

"This Agreement will begin on the Effective Date and will continue in effect until January 16, 2027, unless terminated earlier as provided in this Agreement. To the extent that a SOW is outstanding at the time of termination of the Agreement, the term of this Agreement shall be extended until the time of the completion of all obligations under that SOW. Sections 3 – 9 and 10(b) – 15 will survive termination of this Agreement."

2. Section 5 of Statement of Work No. 1 is hereby deleted in its entirety and replaced with the following:

"Termination Date: January 16, 2027"

- 3. Except as provided in this Amendment No. 1, capitalized terms used in this Amendment No. 1 that are not otherwise defined herein shall have the respective meanings ascribed to them in the Agreement.
- 4. This Amendment No. 1 embodies the entire agreement between the Parties with respect to the amendment of the Agreement. In the event of any conflict or inconsistency between the provisions of the Agreement and this Amendment No. 1, the provisions of this Amendment No. 1 shall control.
- 5. Unless expressly amended by this Amendment No. 1, all other terms of the Agreement remain in full force and effect.
- 6. This Amendment No. 1 may be executed in one or more counterparts, each of which are deemed an original, but both of which together shall constitute one and the same instrument.

7. IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to be executed by their duly authorized representatives as of the Effective Date.

`dynavaxSignerDateField_y2iAgX2]`

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**Dynavax Technologies Corporation**

By: /s/ David Novack`dynavaxSignerSignature_cwh0H`  
Name: David Novack`dynavaxSignerName_WeOrlkK]`  
Title: President & Chief Operating Officer `dynavaxSignerTitle_0gvBbOO]`  
Date: 07-Feb-2025

**Peter Paradiso**

By: /s/ Peter Paradiso `counterpartySignerSignature_MEFnvJW]`  
Name: Peter Paradiso `counterpartySignerName_QDetmiv]`  
Title: Consultant `counterpartySignerTitle_AhsO5ut]`  
Date: 07-Feb-2025 `[counterpartySignerDateField_MxThsBd]`

Exhibit 10.11

DYNAVAX TECHNOLOGIES CORPORATION

## NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

EFFECTIVE JANUARY 2025

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

### EQUITY COMPENSATION

#### Initial Grant; Subsequent Grant

Each Non-Employee Director shall be granted, automatically and without further action by the Board or the Compensation Committee of the Board, a Nonstatutory Stock Option (“**NSO**”) and a Restricted Stock Unit Award (“**RSU**”), together equal to the stock option equivalent of 57,000 shares of Common Stock (collectively, an “**Initial Grant**”) on the date on which such Non-Employee Director is first appointed or elected to the Board, using the methodology and subject to the terms and limitations and described below.

In addition, on the date of and immediately following each annual meeting of the Company’s stockholders, each Non-Employee Director who continues as a Non-Employee Director following such annual meeting shall be granted, automatically and without further action by the Board or the Compensation Committee of the Board, an NSO and an RSU, together equal to the stock option equivalent of 38,000 shares of Common Stock (collectively, a “**Subsequent Grant**”), using the methodology and subject to the terms and limitations and described below. Each Non-Employee Director’s first Subsequent Grant shall be pro-rated as follows based on the number of months that have elapsed since the date on which such Non-Employee Director was first appointed or elected to the Board:

<u>Service Period from Initial Date of Appointment or Election</u>	<u>Pro-Rated Subsequent Grant</u>
10 months or more	100% of grant (option equivalent of 38,000 shares)
7 months or more, but less than 10	75% of grant (option equivalent of 28,500 shares)
4 months or more, but less than 7	50% of grant (option equivalent of 19,000 shares)
1 month or more, but less than 4	25% of grant (option equivalent of 9,500 shares)
Less than 1 month	No grant

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

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

between the 2018 Plan, or any successor plan, and this Non-Employee Director Compensation Plan, this Non-Employee Director Compensation Policy shall control.

#### **NSO Vesting; RSU Vesting and Settlement**

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

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

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

#### **NSO Exercise Price; RSU Consideration**

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

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### **CASH COMPENSATION**

#### **Annual Fees**

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

#### **Committee Fees**

The Chairperson of the Audit Committee shall receive an annual retainer of \$25,000, and each additional member of the Audit Committee shall receive an annual retainer of \$12,500.

The Chairperson of the Compensation Committee shall receive an annual retainer of \$20,000, and each additional member of the Compensation Committee shall receive an annual retainer of \$10,000.

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

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

#### **Pro-Rated Fees and Limit on Fees**

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

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

#### **Travel and Related Costs**

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

**Exhibit 10.24**

#### **6. Addendum**

**to the rental agreement dated December 27, 2006**

**(No. 9.2077.11.03)**

**with 1st addendum from July 1st / 5th, 2019**

**2. Addendum from July 30th / August 11th, 2020**

**3. Addendum from November 11th / December 3rd, 2020**

**4. Addendum from September 13, 2021**

**and 5th addendum dated February 7, 2023**

#### **Object:**

**Eichsfelder Straße 1-11, 40595 Düsseldorf between**

**Onyx Düsseldorf S.à r.l.**

**2-4, Rue Eugène Ruppert**

**2453 Luxembourg**

**Luxembourg**

**a limited liability company (société à responsabilité limitée) incorporated and existing under the laws of the Grand Duchy of Luxembourg and registered in the Luxembourg Commercial Register (registre de commerce et des sociétés) under RCS No. B 111201**

**represented by the sole managing director Mileway DirectorCo S.A.,**

This in turn is represented, as stated in the signature line, either by a managing director with sole power of representation or by one of the authorized representatives Monica Nardon, Véronique Colson, Nina Leclerc or Aline Foucault, who are authorized to represent each other individually based on the power of attorney dated August 3, 2023 - a copy of which is attached to this contract as Annex NT6-V1,

(also called "landlord")

and

**Dynavax GmbH**

Eichsfelder Str. 11

40595 Düsseldorf registered in the commercial register B at the Düsseldorf district court under HRB number 20023

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VAT ID number DE119436703,

represented by one of the two managing directors named below with individual power of representation

Dr. Hans Eric Frings

Dr. Andreas Richter

(also called "tenant")

(Landlord and tenant hereinafter also referred to as "party" or collectively "parties")

## I

### General

There is a rental agreement between the parties dated December 27, 2006 (No. 9.2077.11.03) with 1st addendum dated July 1st / 5th July 2019, 2nd addendum dated July 30th / August 11th, 2020, 3rd addendum dated July 11th. November / December 3, 2020, 4th addendum dated September 13, 2021 and 5th addendum dated February 7, 2023 (hereinafter collectively referred to as the "rental agreement"). The parties first confirm the agreements made in the rental agreement and their position as landlord and tenant, unless other agreements are made in this addendum.

All definitions used in the rental agreement remain valid and are used in this addendum as in the rental agreement, unless otherwise agreed in this addendum.

## II.

### Additions and changes to previous agreements

#### 1 rental additional NT6

1.1 In addition to the previous rental property on the property at Eichsfelder Straße 1-11 in 40595 Düsseldorf, the landlord rents out the following area with a total size of approx. 422 m², which is marked in color in Appendix NT6-1.1 (the "additional area NT6"), for commercial purposes Use by the tenant:

Office space, 1st floor, Eichsfelder Straße 1 approx. 422 m² (marked in red)

1.2 The additional area NT6 will be included in the rental property in accordance with the rental agreement with effect from January 1, 2024.

1.3 The area information is not used to determine the additional area NT6 due to possible measurement errors. The spatial scope of the rented property results from the number and description of the rented areas. The tenant is aware of the additional area NT6. Any deviations in area have no effect on the rights and obligations of the parties under this contract.

1.4 The tenant has inspected the additional area NT6 in detail before completing this addendum and recognizes the condition of the additional area NT6 as suitable for his rental purposes. The tenant takes over the additional area NT6 as seen.

1.5 The handover of the additional area NT6 takes place at the start of the rental period for the additional area NT6. When the additional area NT6 is handed over, a handover protocol will be drawn up

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to be signed by the landlord and tenant. The handover protocol therefore only documents the condition of the additional area NT6 and specifies existing contractual performance obligations. Changes to the contract may not be noted in the handover protocol, but require a formal addendum signed by both parties.

1.6 The additional space is rented exclusively for use as an office.

## 2 Rental item and term

2.1 The rental agreement for the additional area NT6 begins on January 1st, 2024 ("Start of rental period for additional area NT6") and has a fixed term until the end of December 31st, 2028 ("Fixed rental period for additional area NT6").

2.2 The tenancy agreement for the office space specified in Section II. Section 1.1 (b) of the 4th addendum to the rental agreement dated September 13, 2021 on the 2nd floor of Eichsfelder Strasse 1 in Düsseldorf (approx. 420 m²) (incorrectly stated as approx. 450 m² in the 5th addendum to the rental agreement dated February 7, 2023) ("extension space NT6") is extended beyond March 31, 2024 until the end of December 31, 2025 for a fixed term.

2.3 The parties note that the rental property is made up of several sub-areas, with different fixed terms agreed for the sub-areas. All rental areas and fixed terms as of January 1, 2024 are summarized below:

### Area designation Size End of fixed rental period

(a) Storage area on the ground floor, Eichsfelder Straße 1 approx. 350 m² 01/31/2026

(b) Office space on the 2nd floor, Eichsfelder Straße 1

(Extension area NT6) approx. 420 m² December 31, 2025

(c) Office space on the ground floor, Eichsfelder Straße 7 approx. 217 m² as of January 31, 2026

(d) Office space on the 1st floor, Eichsfelder Straße 1

(Additional area NT6) approx. 422 m² December 31, 2028

2.4 For the entire rental property, the rental agreement with respect to the respective partial areas ends automatically upon expiry of the date specified in Section 2.3 as "end of fixed rental period" without the need for termination.

2.5 The rental agreement cannot be properly terminated during the (respective) fixed rental period. The right to extraordinary termination remains unaffected. Partial terminations are not permitted.

2.6 If the tenant continues to use the rental item after the rental period has expired, the rental agreement is not considered to have been extended for an indefinite period. § 545 BGB does not apply.

## 3 Rent / value protection

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3.1 The total monthly rent to be paid for the additional area NT6 from the start of the rental period is:

Basic rent for additional space NT6 EUR 4,152.48

plus advance payment for operating costs for additional area NT6 EUR 1,055.00

Total net rent for additional space NT6 EUR 5,207.48

plus applicable sales tax, currently 19% EUR 989.42

Total rent for additional space NT6 EUR 6,196.90

3.2 The landlord grants the tenant a rent-free period for the additional area NT6 in accordance with the following conditions:

The months of January 2024, February 2024, January 2025, February 2025, January 2026 and February 2026 are free of basic rent for the additional area NT6. During this time, however, the operating costs must be paid with the advance payments plus the respective sales tax. If costs or cost limits relate to the basic rent as a percentage, the above-mentioned basis will still be used as a basis even during the rent-free period.

3.3 The landlord grants the tenant a rent-free period for the extension area NT6 in accordance with the following conditions:

The months of January 2024 up to and including February 2024 are free of basic rent for the additional area NT6. During this time, however, the operating costs must be paid with the advance payments plus the respective sales tax. If costs or cost limits relate to the basic rent as a percentage, the above-mentioned basis will still be used as a basis even during the rent-free period. regular basic rent set.

3.4 The rent for the additional area NT6 is subject to the value protection clause in accordance with Section 5 of the 4th Addendum in the version of Section 2.2 of the 5th Addendum ("value protection clause") with the proviso that the first rent adjustment for the additional area NT6 is effective April 1, 2025 Ratio to the index level for January 2024.

The further rent adjustments are then made for the entire rental property including additional space in accordance with the value protection clause on April 1st of each year in the percentage ratio in which the monthly average CPI (monthly index) has changed compared to the level in April of the respective previous year, without a request or notification from one of the parties is required.

The regulations for securing value with regard to the remaining areas of the rental property continue to apply unchanged.

#### 4 Rental security

4.1 Immediately after signing this addendum, but no later than March 31, 2024, the tenant will provide a rental security in the amount of a total of 100% to secure all direct and indirect claims of the landlord from this rental agreement, including all post-contractual claims against the landlord

**EUR 46,234.52.**

4.2 The tenant already has a bank guarantee from September 21, 2023 from Deutsche Bank AG (guarantee no. 300BGI2301241) in the amount of

**EUR 37,416.53**

provided. A copy of this deed of guarantee is attached to this addendum as Annex NT6-4.2. The guarantee erroneously contains a reference to the 5th addendum dated December 31, 2022, but the 5th addendum was concluded on February 7, 2023. Furthermore, the Guarantee contains a provision stating that it will only come into force if the deed N. 300BGI0800753 is returned to the Guarantor (the "Condition").

4.3 The tenant will, at his discretion, provide the landlord within the period specified in section 4.1 of this addendum either:

(a) with regard to the guarantee specified in Section 4.2 of this addendum, send a declaration of extension from the guarantor, which shows that the above-mentioned guarantee secures all claims from this tenancy in view of the provisions in this addendum (extension of the term, expansion of the area),

and

(b) an additional rental security for the additional area NT6 for the amount of EUR 8,817.99, through an unlimited, irrevocable, unconditional and directly enforceable guarantee from a bank, insurance company or savings bank with its registered office or branch in Germany, whereby the guarantor raises the objection of set-off (Section 770 Paragraph 2 BGB) - except for undisputed or legally established claims -, the challenge and advance action (Sections 770 Paragraph 1, 771 BGB) and must waive the right to deposit;

or

(c) provide a new rental security for the amount specified in Section 4.1, through an unlimited, irrevocable, unconditional and directly enforceable guarantee from a bank, insurance company or savings bank with its registered office or branch in Germany, whereby the guarantor responds to the defense of set-off (§ 770 para . 2

BGB) - except in the case of undisputed or legally established claims, the challenge and advance action (§§ 770 para. 1, 771 BGB) and must waive the right to deposit. After receiving the new, contractual rental security, the landlord will issue the bank guarantee specified in Section 4.2 of this addendum to the tenant.

## 5 Structural measures by the tenant / construction cost subsidy

5.1 The tenant will carry out the following structural measures ("construction measures NT6") at his own expense:

(a) On the office space on the 2nd floor of Eichsfelder Straße 1 (section 2.3 (b) above, extension area NT6), the tenant will install partition walls with doors in the rear area, as in the offer enclosed as appendix NT6-5.1(a). described.

(b) On the office space on the 1st floor of Eichsfelder Straße 1 (section 2.3 (d) above, additional area NT6), the tenant will replace the floor covering with a new floor covering (carpet), as shown in Appendix NT6-6.1(b) described in the enclosed offer and replace the kitchen unit. The kitchen unit must at least correspond to the existing kitchen unit in terms of position, scope and equipment.

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The construction work NT6 will be carried out in accordance with the provisions of the rental agreement, in particular Section 9 of the original rental agreement dated December 27, 2006, unless and to the extent that nothing different is agreed in this addendum.

5.2 The landlord grants the tenant a construction cost subsidy of a maximum of EUR 15,000 plus applicable sales tax. This construction cost subsidy can only be used for the work listed in section 5.1 above.

The tenant can claim this amount by submitting an invoice that meets the requirements of Sections 14, 14a UStG and submitting invoices for paid tradesmen's invoices for fully provided and essentially defect-free services in accordance with Section 5.1 - which have been accepted by the tenant with the involvement of the landlord or a third party commissioned by the landlord were retrieved from the landlord. The construction cost subsidy will expire if and to the extent that it has not been claimed by September 30, 2024.

5.3 At the end of the lease, the tenant is neither entitled nor obliged to dismantle the NT6 construction work. The partition walls, the new floor covering and the new kitchen remain in the rental property without compensation at the end of the rental agreement.

5.4 The obligation to carry out cosmetic repairs, maintenance and repair of the components installed as part of the NT6 construction measures as well as to bear the costs for these measures is carried out in accordance with the distribution of burdens regulated in the rental agreement.

## 6 Continuation

All other provisions of the rental agreement remain valid, unless otherwise stipulated in this addendum, and apply accordingly to this addendum.

### III.

#### Miscellaneous

1 The law of the Federal Republic of Germany applies, excluding conflict of law provisions.

2 The parties confirm that the rental agreement including this addendum contains all agreements made between the parties. Changes and additions as well as contract cancellation and termination must be made in writing. There are no additional verbal agreements. If verbal additional agreements do exist, they are hereby canceled as a precautionary measure.

3 Even if the landlord employs a property manager for the technical and/or commercial management of the property, the landlord remains exclusively entitled to receive notices of termination or option exercise with reference to the rental agreement. Regardless of its appearance towards the tenant, the property management is not authorized by the landlord to accept declarations of termination or exercise of options from the tenant with regard to the rental agreement, unless such authorization is expressly granted to the property manager in writing.

4 The parties are aware of the special statutory written form requirement of Sections 578, 550 Sentence 1 Known in accordance with Section 126 of the German Civil Code (BGB). You undertake to combine the

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rental agreement and this addendum and its appendices into one document in such a way that the requirements for maintaining the written form are satisfied.

Aware of the case law of the Federal Court of Justice on the question of the effectiveness of so-called written form healing clauses, the parties confirm that they want to adhere to the rental agreement including this addendum and will - if and to the extent possible - waive in particular the right to rely on a defect in the written form in accordance with Section 578, 550 Sentence 1 i. V. m. § 126 BGB to invoke and to terminate the rental agreement prematurely citing non-compliance with the written form. This applies to the (original) rental agreement including its appendices as well as this addendum as well as to all possible future addendums, changes and supplementary agreements.

The parties are also aware of the case law of the Federal Court of Justice, according to which a purchaser of the property who enters into the rental agreement in accordance with Section 566 of the German Civil Code (BGB) is generally not bound to the written healing clause in accordance with the previous paragraph. To clarify, the parties therefore note that the written healing clause in accordance with the previous paragraph does not intend to bind such a purchaser of the property. If one of the parties has entered into this rental agreement in accordance with Sections 566, 578 of the German Civil Code (BGB) or based on corresponding legal standards, their legal rights remain unaffected.

5 Should one or more provisions of the rental agreement or this addendum be or become ineffective, should there be a gap or should one of the contractual provisions prove to be unenforceable, this will not affect the legal validity of the other provisions or the rental agreement as a whole. § 139 BGB is expressly excluded and is not intended to act as a rule on the burden of proof. In this case, the parties are obliged to agree on a new provision that corresponds to what is legally and economically intended.

6 If the legal form of the tenant changes, if there are changes in the commercial register, the business registration, the composition of the shareholders or other contexts that are important for the tenancy, the tenant must notify the landlord of this immediately.

7 The landlord is entitled to pass on the data collected within the scope of this contract to the asset manager and property manager for the purposes of rental management. This can also be a third party. If personal data is collected within the scope of this contract, the tenant ensures that there is effective consent from the person concerned to the transmission of his or her personal data to the asset manager and property manager for the purposes of rental management and for the processing of the data by the asset manager and property managers for this purpose.

The landlord is entitled to pass on the data relating to the contractual relationship to potential prospective buyers of the property as well as to banks as part of loans or syndications. If personal data is collected within the scope of this contract, the tenant ensures that there is effective consent from the person concerned to the transmission of his or her personal data to prospective buyers of the property and to banks for purchasing purposes or for the purposes of granting loans or syndication, as well as for the processing of the personal data from prospective buyers and banks for the aforementioned purposes.

If and to the extent that personal data is transferred to a third country, i.e. to a country outside the European Union, the landlord will ensure that an adequate level of data protection exists or is established using the means provided for in the General Data Protection Regulation.

The processing of personal data by the landlord takes place in compliance with and compliance with the provisions of the General Data Protection Regulation. Further details on data processing by the landlord

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can be found at: <https://mileway.com/tpn/>. In the event of subletting, the tenant ensures that he fulfills his own data protection obligations towards his subtenant.

8 At the landlord's request, the tenant will provide a declaration from which it will be clear (e.g. for a possible prospective buyer of the property) that the original rental agreement with its addenda, which must be named in the declaration, represents the entire rental agreement (so-called declaration of completeness).

9 The following appendices are essential parts of this addendum and are deemed to have been agreed:

**Appendix NT6-V (authority dated August 3, 2023)**

**Appendix NT6-1.1 (site plan for additional area NT6)**

**Appendix NT6-4.2 (Copy security deposit)**

#### Appendix NT6-5.1(a) (offer 2nd floor)

#### Appendix NT6-5.1(b) (offer 1st floor)

10 If this addendum is initially signed by only one party and handed over or sent to the other party for signature, this is considered an offer to conclude the addendum, which the other party can effectively accept within a period of one month in accordance with Section 148 of the German Civil Code (BGB). This deadline is due to the fact that the landlord is based abroad, which leads to extended postal delivery times. The date of signing is decisive in each case. This deadline can also be extended by the first signatory in writing or in text form.

11 If this addendum for a party that is a majority of persons or a legal entity is not signed jointly by all authorized representatives, the respective signatory hereby confirms that he is authorized to represent the party and, if necessary, also those who do not sign themselves authorized representative.

Düsseldorf, 04-01-24                      Luxembourg, 04-01-24

Location, date                      Location, date

**For the tenant: For the landlord:**

**/s/ Andreas Richter and /s/ Eric Frings                      /s/ Aline Foucault**

Name: Andreas Richter and Eric Frings                      Name: Aline Foucault

Position: Managing Director                      Position: Managing Director / based on power of attorney dated August 3, 2023

**Exhibit 10.26**

#### **FIRST AMENDMENT TO LEASE**

(Dynavax Technologies Corporation – 2100 Powell)

THIS FIRST AMENDMENT TO LEASE ("**Amendment**") is dated effective and for identification purposes as of December 2, 2024 (the "**Effective Date**"), and is made by and between SPUS8 2100 POWELL, LP, a Delaware limited partnership ("**Landlord**"), and DYNAVAX TECHNOLOGIES CORPORATION, a Delaware corporation ("**Tenant**").

#### **RECITALS:**

WHEREAS, Landlord and Tenant entered into that certain Office Lease dated March 15, 2022 ("**Lease**"), pertaining to the premises currently comprised of a total of approximately 8,053 rentable square feet of space, commonly referred to as Suite 720 ("**Premises**"), of 2100 Powell Street, Emeryville, California 94608 ("**Building**"); and

WHEREAS, Landlord and Tenant desire to enter into this Amendment to extend the Term of the Lease and provide for certain other matters as more fully set forth herein;

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained herein, the parties agree that the Lease shall be amended in accordance with the terms and conditions set forth below.

**1. Definitions.** The capitalized terms used herein shall have the same definitions as set forth in the Lease, unless otherwise defined herein.

**2. Extension.** The parties hereby acknowledge and agree that the Term of the Lease is presently scheduled to expire on July 31, 2025. However, Landlord and Tenant desire to extend the Term of the Lease on the terms and conditions set forth herein. Accordingly, subject to the terms and conditions set forth in this Amendment, the Term of the Lease is hereby extended for an additional period of thirty-six (36) months ("**Extension Term**"), commencing on August 1, 2025, and expiring on July 31, 2028 ("**Extension Expiration Date**"). The parties hereby acknowledge and agree that Tenant shall have no further options or rights to renew or extend the Lease, except as specifically set forth in Section 5 below. Except as otherwise specifically stated herein, Tenant hereby accepts the Premises in its present "as-is" condition.

### 3. Rent.

a. Notwithstanding anything in the Lease to the contrary, effective as of December 1, 2024 and continuing through the Extension Term, Tenant shall pay to Landlord Base Rent in monthly installments as follows:

Dates	Rate/RSF	Monthly Installment
12/02/24 – 12/31/24	\$4.30	\$33,510.90 <sup>1</sup>
01/01/25 – 07/31/25	\$4.30	\$34,627.90
08/01/25 – 10/31/25	\$4.30	\$ 0.00*
11/01/25 – 11/30/25	\$4.43	\$ 0.00*
12/01/25 – 10/31/26	\$4.43	\$35,674.79
11/01/26 – 10/31/27	\$4.56	\$36,721.68
11/01/27 – 07/31/28	\$4.70	\$37,849.10

<sup>1</sup>Prorated for one (1) day at \$1,117.03 per diem.

\* Notwithstanding anything herein to the contrary, Landlord shall abate one hundred percent (100%) of the full monthly installments of Base Rent due for the months of August 2025, September 2025, October 2025 and November 2025 (the “**Abatement Period**”) as set forth above (the “**Abatement**”). Such Abatement shall apply solely to payment of the monthly installments of Base Rent due during such Abatement Period and shall not be applicable to any other charges, expenses, or costs payable by Tenant under the Lease or this Amendment, including, without limitation, Tenant’s obligation to pay Additional Rent and its utilities. In the event that Tenant defaults under the terms and conditions of the Lease or this Amendment beyond any applicable notice and cure period and Landlord elects to terminate this Lease or recovers possession of the Premises through judicial means, the unamortized portion of all conditionally abated Base Rent shall become fully liquidated and immediately due and payable (without limitation and in addition to any and all other rights and remedies available to Landlord provided herein or at law and in equity) as of the date of Landlord’s termination.

b. Except as otherwise set forth herein, Base Rent shall be payable pursuant to Article 3 of the Lease, and Tenant shall continue to pay any and all Additional Rent, including, without limitation, Tenant’s Proportionate Share of Operating Expenses and Taxes, and other amounts due and payable under the Lease.

c. Notwithstanding the foregoing, effective as of the Effective Date hereof, the terms “**Expense Base Year**” and “**Tax Base Year**” shall mean calendar year 2025.

4. **Relocation.** Landlord’s relocation right as set forth in Article 19 of the Lease is hereby deleted in its entirety and of no further force or effect.

### 5. Renewal Option.

a. Provided Tenant is not in default of any term or condition at the time of its exercise of notice beyond any applicable notice and cure period, Tenant shall have the right and option to renew the Lease for the entire Premises for one (1) additional and consecutive period of three (3) years (the “**Renewal Term**”) under the same terms and conditions as stated in the Lease (“**Renewal Option**”), with

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the exceptions that (a) Tenant shall have no further renewal options to renew the Lease and (b) monthly Base Rent, including the annual escalations for each lease year of the Renewal Term, for the Renewal Term shall be one hundred percent (100%) of the Market Rental Rate, as defined and determined in accordance with the

provisions set forth herein. The Renewal Option shall be exercisable by Tenant or any Permitted Transferee of Tenant, if at all, only by timely delivery to Landlord of written notice of election ("**Tenant's Renewal Notice**") at least nine (9) months, but not more than twelve (12) months prior to the Extension Expiration Date. The Renewal Option herein granted shall be deemed to be personal to Tenant and any Permitted Transferee, but if Tenant assigns the Lease to another party other than a Permitted Transferee, such option shall lapse and be of no further force or effect. As they apply to Tenant's right to extend the term of the Lease, the parties acknowledge and agree that the terms "extend," "extension," "renew," and/or "renewal" shall be deemed the same. Upon any renewal of this Lease pursuant to the terms of this Section 5, Landlord and Tenant shall execute and deliver an amendment to this Lease confirming the same; provided that the failure to so enter into such amendment shall not vitiate Tenant's election nor the leasing of the Premises for the Renewal Term in accordance with the terms hereof.

b. For purposes of this Lease, the term "**Market Rental Rate**" shall mean the then prevailing market rental rate that would be agreed upon between a willing landlord and a willing tenant entering into a lease or lease renewal for comparable Class A office space and taking into account all relevant factors including, without limitation, the location, configuration, size and use in a comparable Class A office building as to quality, size, location, view, reputation and age located in the submarket surrounding the Complex ("**Comparable Building(s)**"), with a comparable build-out and a comparable term assuming the following: (1) the landlord and tenant are informed and well-advised and each is acting in what it considers its own best interests; (2) the tenant will continue to pay Tenant's Share of Operating Expenses for the Adjustment Year over and above the Expense Base Year and Tenant's Share of Taxes for the Adjustment Year over and above the Tax Base Year; and (3) the Market Rental Rate takes into consideration all then-applicable market tenant concessions. The determination of the Market Rental Rate shall be in accordance with Sections 5(c)(1) and (2) below.

c. (1) Within thirty (30) days after Landlord's receipt of Tenant's Renewal Notice, Landlord shall provide to Tenant in writing Landlord's determination of the Market Rental Rate for the Renewal Term ("**Landlord's Notice**"). If Tenant agrees with the Market Rental Rate for the Renewal Term set forth in Landlord's Notice, the parties shall promptly enter into an amendment to the Lease documenting the same. If Tenant disagrees with the Market Rental Rate for the Renewal Term set forth in Landlord's Notice, Tenant shall provide written notice ("**Tenant's Notice**") to Landlord within ten (10) days of receipt of Landlord's Notice, and Landlord and Tenant shall proceed to negotiate in good faith to determine the Market Rental Rate for the Renewal Term within thirty (30) days following Landlord's receipt of Tenant's Notice ("**Negotiation Period**").

(2) If Landlord and Tenant have not agreed upon the Market Rental Rate applicable to the Premises within the Negotiation Period, then Landlord and Tenant shall each appoint a broker not later than ten (10) days following the end of the Negotiation Period. If Landlord's broker and Tenant's broker have failed to agree upon the Market Rental Rate within thirty (30) days after the end of the Negotiation Period, the two (2) appointed brokers shall appoint a third broker (within five (5) business days following the expiration of said thirty (30) day period), and the third broker shall select either Landlord's broker's determination of the Market Rental Rate or Tenant's broker's determination of the Market Rental Rate. If either Landlord or Tenant fails to appoint a broker within the prescribed time period, the failing party shall pay to the other party as liquidated damages One Hundred Dollars (\$100.00)

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per day for each day following the deadline that such party fails to appoint a broker, not to exceed Five Hundred Dollars (\$500.00). If the two (2) appointed brokers fail to agree upon a third broker, then the parties shall have the local office of the American Arbitration Association appoint the third broker and the parties shall share equally in the cost of such arbitration. Each party shall bear the costs of its own broker, and the parties shall share equally the cost of the third broker, if applicable. Each broker shall have at least ten (10) years' experience in the leasing of Comparable Buildings and shall be a licensed real estate broker, and the third broker shall be independent.

6. **Security Deposit.** Landlord and Tenant acknowledge and agree that Landlord is currently holding a Security Deposit in the amount of Forty Thousand Nine Hundred Nine and 24/100ths Dollars (\$40,909.24) pursuant to Article 4 of the Lease, and Landlord shall continue holding such Security Deposit for the Extension Term pursuant to the terms of the Lease.

7. **Brokers.** Tenant hereby represents and warrants to Landlord that Tenant has not dealt with any real estate brokers or leasing agents, except Cresa Global, Inc., who represents Tenant, and Landlord hereby represents and warrants to Tenant that CBRE, Inc. is the sole real estate broker or leasing agent representing Landlord (collectively the "**Brokers**"). Landlord shall be solely responsible for the payment of any and all fees and commissions due to Brokers in connection with this Amendment pursuant to the terms of a separate written agreement(s). No commissions are payable to any party claiming through Tenant as a result of the consummation of the transaction contemplated by this Amendment, except to Brokers, if applicable. Tenant hereby agrees to indemnify and hold Landlord harmless from any and all loss, costs, damages or expenses, including, without limitation, all reasonable attorneys' fees and disbursements by reason of any claim of or liability to any other broker, agent, entity or person claiming through Tenant (other than Brokers) and arising out of or in connection with the negotiation and execution of this Amendment. Landlord hereby agrees to indemnify and hold Tenant harmless from any and all loss, costs, damages or expenses, including, without limitation, all reasonable attorneys' fees and disbursements by reason of any claim of or liability to any other broker, agent, entity or person claiming through Landlord (other than Brokers) and arising out of or in connection with the negotiation and execution of this Amendment.

**8. Governing Law.** This Amendment is governed by federal law, including without limitation the Electronic Signatures in Global and National Commerce Act (15 U.S.C. §§ 7001 *et seq.*) and, to the extent that state law applies, the laws of the State of California without regard to its conflicts of law rules.

**9. Counterparts; Electronic Signatures.** This Amendment may be executed in counterparts, including both counterparts that are executed on paper and counterparts that are in the form of electronic records and are executed electronically. An electronic signature means any electronic symbol or process attached to or logically associated with a record and executed and adopted by a party with the intent to sign such record, including facsimile or e-mail electronic signatures. All executed counterparts shall constitute one agreement, and each counterpart shall be deemed an original. The parties hereby acknowledge and agree that electronic records and electronic signatures, as well as facsimile signatures, may be used in connection with the execution of this Amendment and electronic signatures, facsimile signatures, or signatures transmitted by electronic mail in so-called pdf format shall be legal and binding and shall have the same full force and effect as if a paper original of this Amendment had been delivered and had been signed using a handwritten signature. Landlord and Tenant (i) agree that an electronic signature, whether digital or encrypted, of a party to this Amendment is intended to authenticate this writing and to have the same force and effect as a manual signature; (ii) intend to be

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bound by the signatures (whether original, faxed, or electronic) on any document sent or delivered by facsimile, electronic mail, or other electronic means; (iii) are aware that the other party will rely on such signatures; and (iv) hereby waive any defenses to the enforcement of the terms of this Amendment based on the foregoing forms of signature. If this Amendment has been executed by electronic signature, all parties executing this document are expressly consenting under the Electronic Signatures in Global and National Commerce Act (“**E-SIGN**”), and Uniform Electronic Transactions Act (“**UETA**”), that a signature by fax, email, or other electronic means shall constitute an Electronic Signature to an Electronic Record under both E-SIGN and UETA with respect to this specific transaction.

**10. Amendments.** The Lease may only be amended by a writing signed by the parties hereto, or by an electronic record that has been electronically signed by the parties hereto and has been rendered tamper-evident as part of the signing process. The exchange of email or other electronic communications discussing an amendment to the Lease, even if such communications are signed, does not constitute a signed electronic record agreeing to such an amendment.

**11. Notices.** All notices required under the Lease and other information concerning this Amendment (“**Communications**”) shall be personally delivered or sent by first class mail, postage prepaid, or by overnight courier. In addition, the Landlord may, in its sole discretion, send such Communications to the Tenant electronically, or permit the Tenant to send such Communications to the Landlord electronically, in the manner described in this Section. Such Communications sent by personal delivery, mail, or overnight courier will be sent to the addresses in Article 1 of the Lease, or to such other addresses as the Landlord and the Tenant may specify from time to time in writing. Communications shall be effective (i) if mailed, upon the earlier of receipt or five (5) days after deposit in the U.S. mail, first class, postage prepaid; or (ii) if hand-delivered, by courier or otherwise (including telegram, lettergram, or mailgram), when delivered. Such Communications may be sent electronically by the Landlord to the Tenant (i) by transmitting the Communication to the electronic address provided by the Tenant or to such other electronic address as the Tenant may specify from time to time in writing; or (ii) by posting the Communication on a website and sending the Tenant a notice to the Tenant’s postal address or electronic address telling the Tenant that the Communication has been posted, its location, and providing instructions on how to view it. Communications sent electronically to the Tenant will be effective when the Communication, or a notice advising of its posting to a website, is sent to the Tenant’s electronic address.

**12. Miscellaneous.** With the exception of those matters set forth in this Amendment, Tenant’s leasing of the Premises shall be subject to all terms, covenants, and conditions of the Lease. In the event of any express conflict or inconsistency between the terms of this Amendment and the terms of the Lease, the terms of this Amendment shall control and govern. Except as expressly modified by this Amendment, all other terms and conditions of the Lease are hereby ratified and affirmed. The parties acknowledge that the Lease is a valid and enforceable agreement and that Tenant holds no claims against Landlord or its agents which might serve as the basis of any other set-off against accruing rent and other charges or any other remedy at law or in equity.

**13. IRC.** If Landlord is advised by its counsel at any time that any part of the payments by Tenant to Landlord under this Lease may be characterized as other than “rent from real property” under either § 512(b)(3) of the United States Internal Revenue Code and its regulations (the “**Code**”), or § 856(d) of the Code, or otherwise as unrelated business taxable income under the Code, then Tenant shall enter into any amendment proposed by Landlord to avoid such income, so long as the amendment does

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not require Tenant to make more payments or accept fewer services from Landlord, than this Lease provides or impose an undue burden on Tenant.

**14. Waiver of Statutory Provisions.** Each party waives the rights and provisions under California Civil Code §§ 1932(2), 1933(4), and 1945. Tenant waives (a) any rights under (i) California Civil Code §§ 1932(1), 1941, 1942, 1950.7, or any similar law, or (ii) California Code of Civil Procedure §§ 1263.260 or 1265.130; and (b) any right to terminate this Lease under California Civil Code § 1995.310.

**15. California Civil Code Section 1938.** Pursuant to California Civil Code §1938(a), Landlord hereby states that the Premises have not undergone inspection by a Certified Access Specialist ("CASp") (defined in California Civil Code § 55.52). Accordingly, pursuant to a California Civil Code § 1938(c), Landlord hereby further states as follows:

A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

In accordance with the foregoing, Landlord and Tenant agree that if Tenant obtains a CASp inspection of the Premises, then Tenant shall pay (i) the fee for such inspection, and (ii) except as may be otherwise expressly provided in this Lease, the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises.

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IN WITNESS WHEREOF, the foregoing First Amendment to Lease is dated effective as of the date and year first written above.

**LANDLORD:**

SPUS8 2100 POWELL, LP,  
a Delaware limited partnership

By: /s/ Brian Ma  
Name: Brian Ma  
Title: Authorized Signatory  
Date: 12/2/2024

By: /s/ Diann Hsueh  
Name: Diann Hsueh  
Title: Vice President  
Date: 12/2/2024

**TENANT:**

DYNAVAX TECHNOLOGIES CORPORATION,  
a Delaware corporation

By: /s/ Kelly MacDonald  
Name: Kelly MacDonald  
Title: CFO  
Date: 12/2/2024

EXHIBIT 10.29

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[\*\*\*]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO  
COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

This Second Amendment to Commercial Manufacturing and Supply Agreement ("**Second Amendment**") is entered into as of the 16th day of January, 2025 ("**Second Amendment Effective Date**"), by and between **Baxter Pharmaceutical Solutions LLC D/B/A Simtra Biopharma Solutions**, a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403 ("**Simtra**"), and **Dynavax Technologies Corporation**, a Delaware corporation having a principal place of business at 2100 Powell Street, Suite 720, Emeryville, California 94608 ("**Dynavax**").

Whereas, Simtra and Dynavax are parties to a Commercial Manufacturing and Supply Agreement dated November 22, 2013, as amended by the First Amendment to Commercial Manufacturing and Supply Agreement effective September 10, 2021 (collectively, the "**Commercial Supply Agreement**");

Whereas, in a transaction that closed on October 1, 2023, Simtra's former parent company, Baxter International Inc., completed the sale of its biopharma solutions business, including Baxter Pharmaceutical Solutions LLC, to two private-equity firms; Baxter Pharmaceutical Solutions LLC now does business under the trade name Simtra; and

Whereas, Simtra and Dynavax wish to amend certain provisions of the Commercial Supply Agreement; and

Whereas, in parallel with entering into this Second Amendment, Simtra and Dynavax are entering into an Amended and Restated Product Addendum for HEPLISAV-B® hepatitis B vaccine which will become effective as of the effective date stated in the Amended and Restated Product Addendum (the "**Amended and Restated Product Addendum**").

Now, Therefore, in consideration of the foregoing recitals and the mutual promises hereinafter set forth, Simtra and Dynavax agree that the following amendment(s) shall be made to the Commercial Supply Agreement, effective as of the Second Amendment Effective Date:

1. Throughout the Commercial Supply Agreement, all references to "**BPS**" are hereby deleted and replaced with "**Simtra**".
2. The definition of "**Purchase Order**" in Article 1 of the Commercial Supply Agreement is hereby amended and restated to read in its entirety as follows:

"**Purchase Order**" shall mean a written order from Dynavax to Simtra which shall specify: (a) the quantity of Product ordered (expressed as a number of Batches) and the size ([\*\*\*], [\*\*\*] or [\*\*\*] as applicable) of Batches; (b) shipping instructions; (c) requested delivery dates; and (d) delivery destinations."

3. Section 2.6 (Amendment) of the Commercial Supply Agreement is hereby amended and restated to read in its entirety as follows:

"**2.6 Amendment.** Each Development Plan, Project Plan, Product Addendum, Regulatory Plan and Quality Agreement may be amended from time to time, as the Parties experience with the development, Production, testing and use of the applicable Product warrants, only upon mutual written agreement of the Parties. In the event that the terms of any Development Plan, Project Plan, Product Addendum, Regulatory Plan or Purchase Order are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties. No Development Plan, Project Plan, Product Addendum, Regulatory Plan or Purchase Order shall be deemed to amend this Agreement, unless otherwise explicitly agreed to in writing by the Parties. Upon execution of any Development Plan, Project Plan, Regulatory Plan, Product Addendum or Quality Agreement, each such plan and agreement shall be deemed to be incorporated by reference as though fully set forth herein and made part of this Agreement. In the event of a conflict between this Agreement and either the Product Addendum or the Quality Agreement, the Product Addendum will prevail for matters relating to HEPLISAV-B production, the Quality Agreement will prevail for matters of quality and this Agreement will control for business, legal, and financial issues."

4. Section 8.1 (Initial Term) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

**"8.1 Term.** This Agreement shall commence on the Effective Date and shall continue through December 31, 2029 (the **"Initial Term"**), unless earlier terminated in accordance with Section 8.2 or Section 8.3 of this Agreement. This Agreement may be renewed for [\*\*\*] [\*\*\*] renewal term(s), if agreed in writing by both Dynavax and Simtra (each a **"Renewal Term"**) at least [\*\*\*] [\*\*\*] prior to the expiration of the Initial Term or a Renewal Term, as the case may be. The Initial Term as may be extended is referred to herein as the **"Term"**."

5. The phrase "this Agreement" as it appears in the Commercial Supply Agreement or this Second Amendment shall be deemed to refer to the Commercial Supply Agreement, as modified by this Second Amendment. The phrase **"Product Addendum"** as it appears in the Commercial Supply Agreement or this Second Amendment shall be deemed to refer to the Amended and Restated Product Addendum.

6. Except as modified by this Second Amendment, the terms of the Commercial Supply Agreement shall continue in full force and effect.

7. This Second Amendment may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Any signature page delivered by facsimile or electronic image transmission shall be binding to the same extent as an original signature page.

**In Witness Whereof**, the parties have caused this Second Amendment to be executed as of the Second Amendment Effective Date by their duly authorized representatives.

**Baxter Pharmaceutical Solutions LLC D/B/A Simtra Biopharma Solutions**

By: /s/ Bo Watkins

Name: Bo Watkins

Title: SVB Sales and Business Management

**Dynavax Technologies Corporation**

By: /s/ David Novack

Name: David Novack

Title: President & Chief Operating Officer

**AMENDED AND RESTATED PRODUCT ADDENDUM  
FOR  
HEPLISAV-B® HEPATITIS B VACCINE**

This Amended And Restated Product Addendum (**"Amended and Restated Product Addendum"**) is entered into as of January 16, 2025 (**"Amended and Restated Product Addendum Effective Date"**), by and between **Baxter Pharmaceutical Solutions LLC D/B/A Simtra Biopharma Solutions**, a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403 (**"Simtra"**), and **Dynavax Technologies Corporation**, a Delaware corporation having a principal place of business at 2100 Powell Street, Suite 720, Emeryville, California 94608 (**"Dynavax"**).

In a transaction that closed on October 1, 2023, Simtra's former parent company, Baxter International Inc., completed the sale of its biopharma solutions business, including Baxter Pharmaceutical Solutions LLC, to two private-equity firms; Baxter Pharmaceutical Solutions LLC now does business under the trade name Simtra.

This Amended and Restated Product Addendum is an addendum to that certain Commercial Manufacturing and Supply Agreement dated November 22, 2013, by and between Simtra and Dynavax (the **"Original Agreement"**), as amended by that certain First Amendment to Commercial Manufacturing and Supply Agreement dated September 10, 2021 and Second Amendment to Commercial Manufacturing and Supply Agreement dated January 16, 2025 (collectively, the **"Amendments"**). As used herein, the term **"Commercial Supply Agreement"** means the Original Agreement, as amended by the Amendments.

Under the Original Agreement, Dynavax and Simtra entered into a Product Addendum for HEPLISAV-B hepatitis B vaccine that was effective November 22, 2013, which was amended and restated in its entirety by the Parties on September 10, 2021 and subsequently amended on June 21, 2022 and November 11, 2022 (but effective as of September 10, 2021) (collectively, the **"Prior Product Addendum"**).

Dynavax and Simtra wish to again amend and restate the Prior Product Addendum in its entirety so as to permit the parties, under the terms and conditions set forth herein, to continue to Produce the Product for commercial sale by Dynavax under this Amended and Restated Product Addendum.

This Amended and Restated Product Addendum may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. Upon the Amended and Restated Product Addendum Effective Date, this Amended and Restated Product Addendum shall be incorporated by reference into the Commercial Supply Agreement, and the Prior Product Addendum shall (i) be replaced with this Amended and Restated Product Addendum and (ii) be of no further force or effect.

**"Simtra"**

**Baxter Pharmaceutical Solutions LLC D/B/A Simtra Biopharma Solutions**

By: /s/ Bo Watkins

Name: Bo Watkins

Title: SVB Sales and Business Management

**"Dynavax"**

**Dynavax Technologies Corporation**

By: /s/ David Novack

Name: David Novack

Title: President & Chief Operating Officer

**Signature Page To Amended And Restated Product Addendum**

**Exhibit A**

**PRODUCT, PRESENTATION AND COMMERCIAL BATCH SIZE**

Product	Presentation
HEPLISAV-B® HEPATITIS B VACCINE	*** standard syringe, with secondary package

**Commercial Batch Size**

Batch Size	*** Batch size <sup>1</sup>
Fill Volume	*** mL fill, *** syringe

Batch Size	*** Batch size
Fill Volume	*** mL fill, *** syringe

Batch Size	*** Batch size
Fill Volume	*** mL fill, *** syringe

<sup>1</sup> Dynavax may order and purchase \*\*\* Batches during calendar year 2025. Simtra will not Produce Product in the \*\*\* Batch size after calendar year 2025.

## Exhibit B

### ANNUAL OBLIGATION AND ANNUAL ORDER MAXIMUM

Dynavax's Annual Obligation and Simtra's Annual Order Maximum for each calendar year during the Initial Term and any Renewal Term is set forth in the table below:

Calendar Year	Annual Obligation	Annual Order Maximum
	Number of Batches	Number of Batches
2025	[***]4,1,2	[***]1,2
2026	[***]4	[***]3
2027	[***]4	[***]
2028	[***]4	[***]
2029	[***]4	[***]
Each calendar year in a Renewal Term	[***]5	[***]5

For each calendar year, each Batch ordered and purchased (regardless of Batch size) will count towards Dynavax's Annual Obligation and Simtra's Annual Order Maximum.

<sup>1</sup> Dynavax may order and purchase [\*\*\*] [\*\*\*] Batches during calendar year 2025 and the [\*\*\*] Batches will count towards Dynavax's Annual Obligation and Simtra's Annual Order Maximum for calendar year 2025. After calendar year 2025, Simtra will no longer Produce Product in the [\*\*\*] Batch size.

<sup>2</sup> [\*\*\*] Process Validation (PPQ) batch(es) in 2025 are not included in Dynavax's Annual Obligation or Simtra's Annual Order Maximum for calendar year 2025. However, as agreed to by the parties, [\*\*\*] batches carried over from calendar year 2024 to calendar year 2025 are included in Dynavax's 2025 Annual Obligation and Simtra's Annual Order Maximum as shown in the table above.

<sup>3</sup> In the event that Dynavax does not [\*\*\*] for its [\*\*\*] Batch size Product by [\*\*\*], Simtra's Annual Order Maximum for calendar year 2026 will increase by [\*\*\*] Batches for a total of [\*\*\*] Batches.

<sup>4</sup> Dynavax's financial obligation for calendar year(s) (i) 2025 is its Annual Obligation of [\*\*\*] Batches as follows: [\*\*\*] Batches at the [\*\*\*] Batch size times the then current Unit price for the [\*\*\*] Batch size plus [\*\*\*] Batches at the [\*\*\*] Batch size times the then current Unit price for the [\*\*\*] Batch (for the avoidance of doubt, [\*\*\*] batches are excluded from the Annual Obligation and Annual Order Maximum and are not included in the calculation of the financial obligation for calendar year 2025), and (ii) 2026 through 2029 is its Annual Obligation as shown in the table above as follows: [\*\*\*] of the Annual Obligation at the [\*\*\*] Batch size times the then current Unit price for the [\*\*\*] Batch and [\*\*\*] of the Annual Obligation at the [\*\*\*] Batch size times the then current price for the [\*\*\*] Batch (each calendar year individually, "**Financial Obligation**"). If at the end of any calendar year Dynavax has not met its Financial Obligation for such calendar year, Dynavax will pay Simtra the difference between the total dollar amount of the Batches Dynavax ordered and purchased in such calendar year and its Financial Obligation for that calendar year. For the avoidance of doubt, Simtra is under no obligation to Produce more than its Maximum Supply Obligation for any calendar year.

<sup>5</sup> At least twenty-four (24) months prior to the beginning of each renewal term, starting with the renewal term beginning calendar year 2030, Dynavax may request an adjustment to its Annual Obligation and Simtra's Annual Order Maximum for the then upcoming renewal term. In the event Simtra agrees to adjust the Annual Obligation and the Annual Order Maximum for any renewal term, the table above will be amended to reflect such adjustments. In the event the parties cannot agree to the adjustments to Dynavax's Annual Obligation and/or Simtra's Annual Order Maximum for any renewal term, Dynavax's Annual Obligation will be [\*\*\*] Batches and Simtra's Annual Order Maximum will remain [\*\*\*] Batches as shown in the table above for Renewal Terms, with flexibility to switch between [\*\*\*] and [\*\*\*] batches.

## Exhibit C

### PRICING

#### A. PRICING FOR [\*\*\*] BATCH SIZE

Table 1: Commercial Pricing for ~[\*\*\*] Batch Sizes

Volume <sup>2</sup>	Manufacturing Price + Finishing Price <sup>1,2,3</sup> [***]	Manufacturing Price + Finishing Price [***] <sup>1,2,3,4</sup>
Up to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] or more Units per calendar year	[***] per Unit	[***] per Unit

<sup>1</sup> The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Simtra separately. The Unit pricing is inclusive of the following secondary packaging materials ([\*\*\*]) [\*\*\*] and, in the case of Unit pricing for Batches Produced [\*\*\*], the additional costs described in footnote 4 to this Table 2.

<sup>2</sup> For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is “trued up” at the end of each calendar year (i.e. the first [\*\*\*] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Simtra at [\*\*\*] (for [\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and the second [\*\*\*] Units will be charged at [\*\*\*] ([\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and so on even if Dynavax purchases over [\*\*\*] Units of commercial Product in a calendar year).

<sup>3</sup> Quoted Unit price assumes the following QC testing: [\*\*\*]. In the event additional or different QC testing is required, the pricing referenced above may change.

<sup>4</sup> The cost of [\*\*\*] [\*\*\*] is included in Unit pricing for Batches Produced for distribution [\*\*\*].

<sup>5</sup> The actual yield may be decreased because of samples and losses during manufacturing and inspection.

Exhibit C-1

## B. PRICING FOR [\*\*\*] BATCH SIZE

Table 1: Commercial Pricing for ~[\*\*\*] Batch Sizes

Volume <sup>2</sup>	Manufacturing Price + Finishing Price <sup>1,2,3</sup> [***]	Manufacturing Price + Finishing Price [***] <sup>1,2,3,4</sup>
Up to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] or more Units per calendar year	[***] per Unit	[***] per Unit

<sup>1</sup> The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Simtra separately. The Unit pricing is inclusive of the following secondary packaging materials ([\*\*\*]) [\*\*\*] and, in the case of Unit pricing for Batches Produced for distribution [\*\*\*], the additional costs described in footnote 4 to this Table 2.

<sup>2</sup> For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is “trued up” at the end of each calendar year (i.e. the first [\*\*\*] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Simtra at [\*\*\*] (for [\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and the second [\*\*\*] Units will be charged at [\*\*\*] ([\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and so on even if Dynavax purchases over [\*\*\*] Units of commercial Product in a calendar year).

<sup>3</sup> Quoted Unit price assumes the following QC testing: [\*\*\*]. In the event additional or different QC testing is required, the pricing referenced above may change.

<sup>4</sup> The cost of [\*\*\*] [\*\*\*] is included in Unit pricing for Batches Produced for distribution [\*\*\*].

<sup>5</sup> The actual yield may be decreased because of samples and losses during manufacturing and inspection.

Exhibit C-2

C. PRICING FOR [\*\*\*] BATCH SIZE

Table 1: Pricing for ~[\*\*\*] Batch Size (Non-GMP Pre PPQ Demonstration Batches and Process Validation Batches)

Batch Type	Batch Size <sup>6</sup>	Price per Batch <sup>1,3</sup>
[***] Batches <sup>4</sup>	Up to [***] syringes per batch	[***] USD
[***] Batches [***]	Up to [***] syringes per batch	[***] USD

Table 2: Commercial Pricing for ~[\*\*\*] Batch Size<sup>6</sup>

Volume <sup>2</sup>	Manufacturing Price + Finishing Price <sup>1,2,3</sup> [***]	Manufacturing Price + Finishing Price [***] <sup>1,2,3,4,5</sup>
Up to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit	[***] per Unit
[***] or more Units per calendar year	[***] per Unit	[***] per Unit

Note: All pricing in this Exhibit assumes automated inspection. In the event manual inspection is required, the pricing referenced above may change.

- <sup>1</sup> The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Simtra separately. The Unit pricing is inclusive of the following secondary packaging materials [\*\*\*] [\*\*\*] and, in the case of Unit pricing for Batches Produced for distribution in the EU and Europe, the additional costs described in footnote 5 to this Table 2.
- <sup>2</sup> For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is “trued up” at the end of each calendar year (i.e. the first [\*\*\*] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Simtra at [\*\*\*] (for [\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and the second [\*\*\*] Units will be charged at [\*\*\*] ([\*\*\*]) or [\*\*\*] ([\*\*\*]) per Unit, as applicable (as adjusted), and so on even if Dynavax purchases over [\*\*\*] Units of commercial Product in a calendar year).
- <sup>3</sup> Quoted Unit price assumes the following QC testing: [\*\*\*]. In the event additional or different QC testing is required, the pricing referenced above may change.
- <sup>4</sup> [\*\*\*] batch price does not include [\*\*\*]. Scope of [\*\*\*] testing will be priced at a later date and mutually agreed to by the Parties in writing.
- <sup>5</sup> The cost of [\*\*\*] [\*\*\*] is included in Unit pricing for Batches Produced for distribution [\*\*\*].
- <sup>6</sup> The actual yield may be decreased because of samples and losses during manufacturing and inspection.

Exhibit C-3

Exhibit Dto Amended and Restated Product Addendum for

HEPLISAV-B® HEPATITIS B VACCINE

Initial Long Range Forecast

Calendar Year	Forecast (Number of Batches)
2025	[***] & [***] <sub>1</sub>
2026	[***] <sub>1</sub> & [***] <sub>1</sub>
2027	[***]& [***]
2028	[***]& [***]
2029	[***]& [***]

<sup>1</sup> Assuming [\*\*\*] [\*\*\*] in time to allow [\*\*\*] beginning [\*\*\*]

Exhibit E to Amended and Restated Product Addendum for

HEPLISAV-B® HEPATITIS B VACCINE

Yield Formulas and Calculations

Once the Yield Rate has been established for a Batch size as set forth in Section 4.5 of the Agreement, after the end of each calendar year thereafter, the Parties shall calculate the average Actual Batch Yield for the Batches of Product released during such calendar year and do a Yield Reconciliation, as defined below.

Definitions:

1. **“Yield Rate”** shall be defined as the average Actual Batch Yield for [\*\*\*] of Commercial Product Produced (including secondary packaging) and released, including samples, for each Batch size.
2. **“Expected Yield”** shall be defined as [\*\*\*] of the established Yield Rate.
3. **“Actual Batch Yield”** shall be defined as Syringes Produced (including secondary packaging) and released for a Batch, including samples, divided by the Theoretical Filled Units, multiplied by one hundred.
4. **“Bulk Solution Final Weight”** is defined in the Master Batch Record.
5. **“Yield Reconciliation”** shall be defined as the Parties reconciling the average Actual Batch Yield as compared to the Expected Yield. The Yield Reconciliation is to be performed and reviewed by both Parties annually, no later than [\*\*\*] days following the end of the applicable calendar year.
6. **“Theoretical Fill”** for a Batch shall be defined as the number of syringes that could have been filled utilizing the Bulk Solution Final Weight of the formulated solution minus total formulation loss divided by the Target Fill Weight as defined in the Master Batch Record.
7. **“Syringes Produced”** shall be defined as the actual number of good syringes filled and packaged, including samples, as defined in the Master Batch Record. Syringes Produced shall be used as the numerator in determining Actual Batch Yield.
8. **“Target Fill Weight”** shall be the weight, used in the Production of each Unit (syringe) of material as defined in the Master Batch Record.

General Information:

- For illustrative purposes, the primary Batch sizes are ~[\*\*\*] and ~[\*\*\*] for the Product.
- Yield Reconciliation shall be completed annually (within [\*\*\*] [\*\*\*] of the end of each calendar year) and will include all Produced Batches released in the prior calendar year.
- Normal rules of rounding shall apply in all calculations.

**Theoretical Fill:**

- Bulk Solution Final Weight (kg) x 1000
- Target Fill Weight = [\*\*\*] g
- Total formulation loss (g)
- Theoretical Fill = [Bulk Solution Final Weight (kg) x 1000 – Total formulation loss (g) ÷ Target Fill Weight (g)]

**Actual Batch Yield:** Calculated for each Batch released during a calendar year

Shall be calculated as follows:

- The *numerator* for Actual Batch Yield shall be the number of Syringes Produced.
- The *denominator* for Actual Batch Yield shall be the Theoretical Fill units.
- Displayed as a percent
- Expressed mathematically:

Actual Batch Yield = (Syringes Produced / Theoretical Fill) \* 100

**Expected Yield:**

Shall be calculated as follows:

- Determine the Yield Rate for the [\*\*\*] commercial batches, including samples, excluding the Process Validation Batches.
- [\*\*\*] of the Yield Rate becomes the Expected Yield.

**Yield Reconciliation Reimbursement:**

In the event the average Actual Batch Yield for all Batches Produced and released during a calendar year is less than the Expected Yield, Simtra will provide a credit to Dynavax for each Unit below the Expected Yield according to the following table:

Configuration	Reimbursement amount (per unit)
HEPLISAV-B® HEPATITIS B VACCINE	Capped at the applicable Unit price as shown in Exhibit C

EXHIBIT 10.30

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[\*\*\*]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL.

**SUPPLY AGREEMENT**

THIS SUPPLY AGREEMENT (this "Agreement") dated January 1, 2025 (the "Effective Date"), is between West Pharmaceutical Services, Inc., a Pennsylvania corporation with an address at 530 Herman O. West Drive, Exton, Pennsylvania 19341 on behalf of itself and its Affiliates ("West"), and Dynavax Technologies

Corporation, a Delaware corporation with an address at 2100 Powell Street, Suite 720, Emeryville, CA 94608 on behalf of itself and its Affiliates ("Customer").

Customer desires to purchase from West, and West desires to sell to Customer, certain pharmaceutical packaging, containment and/or delivery products on the terms and subject to the conditions set forth below. Accordingly, the parties hereto, intending to be legally bound, agree as follows:

1. Agreement to Sell and Purchase Products.

- a. Product Scope. The products that are the subject of this Agreement are described in Exhibit A (the "Products"). Additional Products may be added to this Agreement from time-to-time by mutual agreement of the parties and documented by West's issuance of a revised product schedule, without the need to formally amend this Agreement. For the avoidance of doubt, supply of West self-injection devices, contract manufactured products, and services are excluded from the scope of this Agreement.
- b. Purchase Commitment. Customer shall purchase from West, at least [\*\*\*] of Customer's requirements for the Products (and goods manufactured by third parties that perform the same function as and could be substituted for, and are substantially similar to the Products) in accordance with the terms and conditions of this Agreement (including if West provides a proposed delivery date in an order acknowledgment that is more than [\*\*\*] months beyond the delivery date proposed by Customer in the applicable purchase order, as described in Section 3(c)). In the event that West is unable to supply Product to Customer in accordance with the terms of this Agreement, Customer's purchase obligation in this section shall be waived until such time as West can recommence the supply of such Product; provided, that Customer will permit West to manufacture any such Products at non-affected West manufacturing plants, subject to such alternate plants' satisfying the quality and regulatory obligations imposed herein on the affected West manufacturing plants.
- c. Affiliates Participation. Customer's Affiliates as of the Effective Date may participate in this Agreement as though they were a party hereto, and the term "Customer" shall be deemed to include such Customer Affiliates. West may perform its obligations hereunder through its Affiliates, and the term "West" shall be deemed to include such West Affiliates. Each party shall be jointly and severally liable for its Affiliates hereunder, and for the avoidance of doubt, failure by a party's Affiliate to comply with any provision of this Agreement shall constitute a breach of this Agreement by such party. The term "Affiliate", with respect to the parties hereto, means

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any corporation or business entity fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by such party, or any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of such party. Customer Affiliates added through acquisition after the Effective Date may participate in this Agreement with West's prior written consent; provided, however, that this participation provision shall not restrict Customer's right to assign the Agreement to an Affiliate pursuant to Section 16(c) below.

- d. Audit. Upon reasonable advance written notice (but in no event less than fifteen (15) business days) and during Customer's normal working hours, West may at its sole cost and expense audit Customer's applicable, agreed-upon purchasing records solely to the extent required to verify Customer's compliance with its obligations in Section 1(b) above (the "Audit"). The Audit shall be conducted by a Big 4 accounting firm designated by West and acceptable to Customer, which shall not be unreasonably withheld. The Audit may be conducted once per [\*\*\*] month period during the Term.
2. Term. This Agreement will commence on the Effective Date and, unless terminated earlier as provided herein, will continue in effect until the [\*\*\*] anniversary thereof (the "Term"); the Term shall automatically extend by successive [\*\*\*] year periods thereafter unless either party provides notice to the contrary to the other party not less than [\*\*\*] months prior to the end of the then-current Term.
3. Purchase Orders and Forecasts.
- a. Orders. Firm orders for Product shall be placed by Customer in writing. All orders shall specify the Product and quantities ordered (which shall be in whole batch size quantities), delivery and shipping instructions, requested delivery dates (consistent with then-current lead times), and such other information as West may reasonably request in order to allow West to fill the order. Minimum lead time on orders will be established by West in writing, but are subject to adjustment by West based on demand for the Products, demand at the facilities at which the Product is manufactured and assembled, and other relevant factors. West shall use commercially reasonable efforts to maintain consistent lead times and agrees to deliver to Customer a written update on the then-current lead time for Products once per year during the Term and upon Customer's written request. Unless otherwise agreed by West in writing, the scheduled delivery date shall be not less than West's then-current lead time for the Product.
  - b. Forecasts. Customer shall deliver to West a Master Production Plan prior to the end of each calendar quarter during the Term that covers Customer's estimated requirements for Products during the following [\*\*\*] month period, including a binding blanket purchase order for the initial [\*\*\*] months (subject to lead time) and [\*\*\*] months' non-binding forecast (the "MPP").
  - c. Acceptance. West will endeavor to acknowledge receipt of each purchase order within five (5) business days; provided, however, that all purchase orders are subject to West's subsequent confirmation and acceptance within ten (10) business days of receipt of such purchase order, which confirmation shall

contain the (i) quantity of Products that West will provide to Customer, and (ii) date of delivery by West of such ordered Products to Customer. If West does not provide such confirmation within such period, then the Parties shall use best efforts to schedule a meeting within a further five (5) business days to discuss the status of the pending purchase order, and confirm the timing for the confirmation as described above. The MPP shall be updated to reflect the West-confirmed estimated delivery dates. Orders accepted by West during the Term shall be fulfilled by West notwithstanding a delivery date that falls outside of the Term.

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- d. Cancellation. Customer may not cancel or modify any order that has been accepted by West except with West's prior written consent, not to be unreasonably withheld, conditioned or delayed; permitted order cancellations or modifications may be conditioned on Customer's payment of West's change/cancellation fees.
- e. Cooperation. The parties agree to meet (in person or by telephone) on a reasonable ad hoc basis upon the request of either party to review and discuss the forecasting, ordering and shipping procedures implemented pursuant to this Agreement.

4. Payment and Delivery Terms.

- a. Payment Terms. Payment terms are net [\*\*\*] days from the date of invoice unless otherwise stated or agreed in writing by West. West may charge Customer a late payment fee up to the maximum amount permitted by applicable law on any unpaid and undisputed amounts each month (or part thereof) such payment is late, not to exceed [\*\*\*] per annum on any unpaid amounts. If Customer in good faith disputes one or more items in an invoice, Customer shall notify West in writing, noting the specifics of its good faith dispute, within ten (10) business days of receipt of an invoice; provided that Customer shall pay the undisputed portion of an invoice as set forth in this Section 4(a). Customer and West may agree to allow West to make delivery in installments, which shall be separately invoiced by West and paid for by Customer. The currency for invoices and payments under this Agreement shall be the U.S. dollar.
- b. Delivery; Risk of Loss. Unless otherwise agreed in writing by the parties, all sales are made according to the Delivered in Place (DAP) INCOTERMS 2020 ("DAP INCOTERMS") which shall be stated on the face of the West order confirmation. Delivery dates are estimates only; West will use commercially reasonable efforts to meet all confirmed delivery dates and will promptly notify Customer if it expects a shipment or delivery will be delayed. Delivery variance of [\*\*\*] more or less than the confirmed quantity shall constitute fulfillment of the order; provided, however that Customer will only be invoiced for the delivered quantity.
- c. Storage. If Products are not shipped within [\*\*\*] after notification has been made to Customer that they are ready for shipping for any reason within Customer's control, including Customer's failure to give shipping instructions, or if Customer otherwise refuses to accept delivery, then regardless of the otherwise applicable DAP INCOTERMS or other INCOTERMS agreed by the parties pursuant to Section 4(b), West may elect to: (i) store the Product either on or off-site at Customer's risk and expense, and Customer will promptly pay all handling, transportation and storage expenses at the prevailing commercial rates following West's submission of invoices for such amounts; and/or (ii) exercise any of the rights and remedies described in Section 15(a), including those related to Customer's failure to make payments as required by this Agreement.

5. Inspection.

- a. Incoming Visual Examination. Customer or its third-party recipient of product delivery in the case of a drop-ship will verify that the shipment is intact and that there is no shortage, loss, or damage or other error in delivery apparent under reasonable visual examination of the incoming shipping cartons or pallets ("Shipping Damage"). Customer will notify West within [\*\*\*] of delivery if the shipment is of any Shipping Damage. Failure by Customer to notify West within [\*\*\*] of delivery will constitute a waiver of all claims for Shipping Damage; provided, the foregoing waiver shall not affect Customer's rights regarding any other failure of the Products to conform to the requirements of this Agreement, including but not limited to latent defects. For orders for which risk of loss transfers at West's facility based on the applicable INCOTERMS agreed to by the parties pursuant to Section 4(b), claims for Shipping Damage by common carrier must be made to the carrier and not to West.

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- b. Product Testing. Customer or its designated third-party recipient of product delivery in the case of a drop-ship shall perform a thorough incoming inspection of the Products within [\*\*\*] of their arrival at the specified destination and shall promptly notify West of any claims that any shipment of Products did not, at the time of delivery, meet one or more of the warranties in this Agreement. Failure by Customer to conduct such incoming inspection and/or to notify West of any nonconformity of the Products to the warranties in this Agreement within [\*\*\*] of their arrival at the specified destination will constitute a waiver of Customer's rights under such warranties; provided, the foregoing waiver shall not affect Customer's rights with respect to latent defects that were not reasonably discoverable through the performance of a thorough incoming inspection. Customer shall report latent defects within [\*\*\*] of discovery, but in any event within the shelf-life of the Product.

- c. Quality Disputes. If Customer and West are unable to agree as to whether any Products meet the warranties in this Agreement, the parties shall cooperate to have the Products in dispute analyzed by an independent testing laboratory of recognized repute selected by Customer and approved by West, which approval shall not be unreasonably withheld, conditioned or delayed. The results of such laboratory testing shall be final and binding on the parties on the issue of compliance of the Products with such warranties. If the Products are determined to meet such warranties, then Customer shall bear the cost of the independent laboratory testing and pay for the Products in accordance with this Agreement. If the Products are determined not to have met such warranties, then West shall bear the cost of laboratory testing and Customer shall be entitled to avail itself of the remedies provided in Section 9(d).
6. Price and Price Adjustments.
- a. Annual Price Adjustment. Product prices for shipments through [\*\*\*], are set forth in Exhibit A hereto. The prices set forth in this Agreement will be increased annually by the percentage increase in the United States Producer Price Index for the Pharmaceutical Preparation Manufacturing Industry (the "PPI Index") issued by the U.S. Bureau of Labor Statistics, which such increase being effective each January 1 during the Term for Products delivered on or after January 1 in the relevant calendar year. Such adjustments shall be made annually on each subsequent anniversary of this Agreement during the Term by comparing the average change in the PPI Index each month over the [\*\*\*] period ending the preceding September 30 against the average change in the PPI Index each month over the immediately preceding [\*\*\*] period. For the avoidance of doubt, such price increases will occur automatically, documented by West's issuance of a revised product schedule, without the need to formally amend this Agreement.
- b. Surcharge. With [\*\*\*] written notice to Customer, West may apply a surcharge based upon sudden or significant increases in the price of raw materials, utilities and other expenses associated with the manufacture or supply of the Products, including without limitation as a result of Force Majeure. The surcharge shall be decreased or eliminated to the extent that underlying raw material, utility or other expenses materially decline. West will periodically provide further written details to Customer regarding the amount of and any adjustments to the surcharge prior to the end of each calendar quarter during the Term.
7. Force Majeure. Neither party hereto assumes any responsibility for any loss or damage occurring by reason of any delay or inability to perform its obligations hereunder or deliver caused by fire, strike, accident, pandemic (including material new developments relating to COVID-19 following the Effective Date), government act, insufficient or failure of regular sources of supply, delay of common carriers or from any other cause which is unavoidable or beyond such party's reasonable control ("Force Majeure"). Should any Force Majeure events occur, the affected party shall give prompt

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- notice to the other party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible. If a Force Majeure event persists for more than [\*\*\*], the parties shall confer and jointly determine a course of action intended to ameliorate the adverse effects of the event; such course of action may include but is not limited to the partial or complete termination of this Agreement. In the event a Force Majeure that prevents West from delivering at least [\*\*\*] of the confirmed orders for more than [\*\*\*], Customer shall have the right to terminate any such orders without breaching Section 1(b) of this Agreement.
8. Allocation of Raw Materials and Production Capacity.
- a. Without limiting Customer's remedies under Section 7, in the event that West's supply of raw materials or other components supplied by third parties or production capacity necessary for the manufacture of any Product is disrupted or adversely affected during the Term of this Agreement, such that any such raw materials or components or production capacity are in short supply for a period of at least [\*\*\*] [\*\*\*], then West shall allocate that portion of the available quantity of such raw materials or components or production capacity to Customer as Customer's consumption of such raw materials or components or production capacity proportionate to West's aggregate use of such raw material or components or production capacity during the [\*\*\*] [\*\*\*] immediately preceding the occurrence of the event giving rise to the short supply or limited production capacity, except to the extent in West's reasonable judgment a different allocation of raw materials or components or production capacity is required to avoid serious harm or injury to third parties.
- b. In the event the disruption in the supply of raw materials or components or production capacity is reasonably expected to continue for an indefinite period, the parties shall jointly consider their available options including the selection of an alternate supplier of the raw material or component, the identification of suitable alternate raw material or component or production capacity and the acquisition of sufficient quantities of the raw material or component or production capacity to enable the continued manufacture of the Product for a reasonable period.
9. Representations, Warranties, Remedies and Limitations of Liability.
- a. Mutual Representations and Warranties. Each party hereto represents that as of the Effective Date: (i) it has the authority to enter into this Agreement; (ii) the individual executing this Agreement on behalf of such party is authorized to do so; and, (iii) there is no action, suit or proceeding, at law or in equity, pending which would materially adversely affect its performance of its obligations hereunder or the other transactions contemplated hereby, or the enforceability of this Agreement. West represents and warrants that during the Term it shall comply with all applicable laws, regulations, and standards concerning its manufacturing and supply obligations arising under this Agreement, including but not limited the United States ("U.S.") Food, Drug and Cosmetic Act and comparable laws or regulations in other countries and all current good manufacturing practices (the "West Compliance Representations"). Customer warrants that during the Term it shall comply with all applicable laws and regulations concerning its purchase and use of the Products, including but not limited the U.S. Food, Drug and Cosmetic Act and comparable laws or regulations in other countries (the "Customer Compliance Representations").

- b. Product Warranty. West warrants only that as of the date of delivery in accordance of the DAP INCOTERMS the Products shall conform to any specifications specifically agreed to in writing by West and Customer or, in the absence of such mutually agreed-to specifications for any Product, the applicable West global master specification (collectively, the "Product Specifications").

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Customer acknowledges and agrees that all Products are sold only on the basis that it is the sole responsibility and duty of Customer to evaluate and test the Products, assure that the Products are fit for the uses and purposes for which Customer intends to use them, and are compatible with Customer's particular product and its processing (including sterilization) and packaging methods. Except to the extent of any obligations expressly imposed on West pursuant to this Agreement, Customer assumes all risks whatsoever as to the result of the use of the Products, whether used singly or in combination with other goods or substances.

- c. Warranty Disclaimer. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, THE UNDERTAKINGS, REPRESENTATIONS, WARRANTIES AND CONDITIONS SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER EXPRESS AND IMPLIED WARRANTIES, UNDERTAKINGS, REPRESENTATIONS, GUARANTEES, AND CONDITIONS, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES AND CONDITIONS OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT OF RIGHTS, ALL OF WHICH ARE EXPRESSLY DISCLAIMED. THE UNDERTAKINGS, REPRESENTATIONS, WARRANTIES AND CONDITIONS IN THIS AGREEMENT ARE GIVEN ONLY TO THE PARTIES HERETO.

- d. Remedies. West will replace any of the Products shown to be nonconforming to the limited Product warranty set forth in this section or, at Customer's option, provide Customer with a credit for the amount paid for the nonconforming Products (the "Warranty Remedy"), provided a claim is made within the timeframes specified in Section 5. Purportedly nonconforming Products shall not be returned without West's prior written approval. West may request that Customer destroy nonconforming Products at West's expense, such destruction to be certified in writing by an appropriate officer of Customer. WHETHER IN TORT (INCLUDING NEGLIGENCE), CONTRACT, WARRANTY OR ANY OTHER LEGAL THEORY OF LIABILITY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW: (I) THE PROVISIONS OF THIS SECTION SET FORTH CUSTOMER'S EXCLUSIVE REMEDY AND WEST'S AND ITS AFFILIATES' AND RELATED PARTIES' SOLE LIABILITY FOR ANY CLAIM RELATING TO PRODUCT OR SUPPLY DEFECT, DELAY OR NONCONFORMITY OR OTHERWISE ARISING OUT OF OR IN CONNECTION TO THIS AGREEMENT; AND (II) IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES OR RELATED PARTIES BE LIABLE FOR: (A) INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL, EXEMPLARY AND/OR CONSEQUENTIAL LOSS OR DAMAGES; OR, (B) EXCEPT AS OTHERWISE EXPRESSLY AGREED HEREIN AND WITHOUT LIMITING ANY PURCHASE OR PAYMENT OBLIGATIONS HEREIN, FOR LOSS OF PROFITS, LOSS OF REVENUE, LOSS OF SALES OR BUSINESS OPPORTUNITY, LOSS OF AGREEMENTS OR CONTRACTS, LOSS OF ANTICIPATED SAVINGS, WASTED EXPENDITURE, COST OF RECALL, COST OF COVER, LOSS OF USE OR CORRUPTION OF SOFTWARE, DATA OR INFORMATION, OR LOSS OF OR DAMAGE TO GOODWILL IN EACH CASE ARISING OUT OF OR IN CONNECTION TO THIS AGREEMENT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

- e. Indemnification.

At West's expense as described herein, West (as the "Indemnitor") shall indemnify, defend and hold Customer, its Affiliates and its and their respective directors, officers, employees and contractors (each, as the "Indemnitee") harmless from and against any third-party claim to the extent caused by or attributable to (i) the failure of the Products to comply with the warranty set forth in Section 9 or (ii) West's breach of the West Compliance Representations by defending against such claim and paying all amounts that a court finally awards or that West agrees to in settlement of such claim; provided, however, that West's indemnification obligation will not apply to the extent the third-party claim arises out of or results from any Customer Indemnitee's negligence, recklessness, willful misconduct or breach of this Agreement.

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- f. At Customer's expense as described herein, Customer (as the "Indemnitor") shall indemnify, defend and hold West, its Affiliates and its and their respective directors, officers and employees (each, as the "Indemnitee") harmless from and against any third-party claim to the extent caused by or attributable to (i) Customer Components; (ii) the IP Indemnification Exclusions; or (iii) Customer's breach of this Agreement (including, without limitation, the Customer Compliance Representations), negligence or willful misconduct on the part of Customer or its contractors in connection with its activities under this Agreement; provided, however, that Customer's indemnification obligation will not apply to the extent the third-party claim arises out of or results from any Indemnitee's negligence, willful misconduct or breach of this Agreement.
- g. The Indemnitee shall promptly notify the Indemnitor of any claim or potential claim covered by the indemnification provisions of this Section, and shall include sufficient information to enable the Indemnitor to assess the facts; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure or delay. The Indemnitor shall have the right to control such defense and all related negotiations. Each party shall cooperate with the

other party in the defense of all such claims; provided, however, that the Indemnitor shall reimburse the Indemnitee for all reasonable expenses incurred by the Indemnitee at the Indemnitor's request. No settlement or compromise that includes any non-monetary provisions shall be binding on a party without such party's prior written consent, which consent shall not be unreasonably withheld or delayed. For the sake of clarity, a "third party" as referenced in this Section means a party other than Customer or the Customer Indemnitees or West or the West Indemnitees. West's sole indemnification arising under this Agreement or relating to the Products is as set forth in this Section. Each party shall use commercially reasonable efforts to mitigate the damages incurred by such party in connection with the Agreement, whether or not those damages are subject to indemnification by the other party.

- h. **Quality Agreement.** West and Customer shall comply with the terms and conditions of that certain Quality Agreement effective as of April 15, 2016, between Customer and West, as amended, supplemented or replaced from time to time, applicable to the manufacture of the products (the "Quality Agreement"), or any other quality agreement that is negotiated and executed subsequently between the parties. The parties agree to use commercially reasonable efforts to meet and confer within [\*\*\*] of the Effective Date to determine whether the Quality Agreement requires amendment, supplement or replacement. The parties further agree that to the extent there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the Quality Agreement shall control with respect to quality issues.

10. **Intentionally Omitted.**

11. **Compliance.**

- a. **Denied Party Screening.** Each of West and Customer shall verify that their respective third-party business partners related to this Agreement are not on government lists of restricted parties, including the European Union European External Action Service ("EEAS") Consolidated Financial

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Sanctions List, the U.S. Denied Persons List ("DPL"), the U.S. Entities List ("EL"), the U.S. Specially Designated Nationals ("SDN") and Blocked Persons List, the OFAC non-SDN Consolidated Sanctions List and the U.S. Unverified List ("UVL").

- b. **Certification Regarding Exclusion.** Each party certifies that it and its employees, directors and officers are not a person or entity are restricted from doing business with under the regulations of the Office of Foreign Asset Control ("OFAC") of the Department of Treasury (including those named on OFAC's Specially Designated and Blocked Persons list) or under any statute, executive order, the USA Patriot Act, Brazil's International Sanctions Law, EU's Common Foreign Security Policy, UK Anti-Money Laundering Act 2018, Australia's Consolidated Sanctions List, or other governmental action or regulations in any of the countries in which West operate. Each party shall provide immediate written notice to the other party if, at any time prior to the execution of or during the term of this Agreement, it becomes aware of an exclusion or sanction, or a threatened exclusion or sanction. The certification in this provision is a material representation of fact upon which reliance was placed when entering into this Agreement. Notwithstanding any provision to the contrary in this Agreement, if it is later determined that either party knowingly rendered an erroneous certification or such certification becomes erroneous by reason of changed circumstances, the other party may terminate this Agreement immediately.
- c. **Anti-bribery.** In all undertakings each party agrees it will make no payments of money, or anything of value, nor will such be offered or promised, directly or indirectly, to any foreign officials, political parties, party officials, candidates for public or political party office, or either party's personnel, to influence the acts of such persons in their official capacity, or to induce them to use their influence to obtain or retain business or gain an improper advantage in connection with any business venture or contract in which such party is a participant. Each party understands that it is the other party's policy to comply with the provisions of the Foreign Corrupt Practices Act of 1977 ("FCPA"), the United Kingdom Bribery Act of 2010 ("U.K. Bribery Act") and any other applicable comparable laws or regulations. Each party agrees to maintain accurate books and records for purposes of complying with the FCPA, the U.K. Bribery Act, China's Anti-Unfair Competition Law (AUCL) 2017 & 2019, Singapore's Prevention of Corruption Act (PCA), and any other applicable comparable laws or regulations in the jurisdictions where the parties operate. The parties agree that any violation of the FCPA, the U.K. Bribery Act or any other applicable comparable laws or regulations by a party, is a material breach of this Agreement, which may then result in immediate termination, with no notice or opportunity to cure.
- d. **Code of Conduct.** Each party represents and warrants that they each have a respective Code of Conduct which can be accessed for West via <https://www.westpharma.com/investors/corporate-governance?#codeofconduct> and for Customer via [DVAX - Code of Business Conduct and Ethics 11 April 2024.pdf \(dynavax.com\)](#). Each party and its employees, directors and officers will abide by their respective Code of Conduct. The parties agree that any actual or potential violation of a Code of Conduct will be reported promptly via email to the other party's respective compliance officer (for West via [\*\*\*], for Customer via [\*\*\*]).
- e. **Data Privacy.** "Personal Data" means any information from which a natural person ("data subject") can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier such as an email address or to one or more other factors specific to that natural person. The parties agree that in the performance of this Agreement, Personal Data in the form of business contact information of one or more of the parties' employees or business partners will be exchanged. The parties agree to use this Personal Data only as necessary to perform under this Agreement and/or as may be required by

applicable law, and further agree to implement reasonable security measures to protect this Personal Data. The parties agree that no other use will be made of this Personal Data unless all necessary agreements to implement appropriate measures for the international transfers or processing of Personal Data and the protection of the data subjects are executed in accordance with applicable data protection laws.

- f. Data Security. Each party shall promptly and without undue delay notify the other party in writing about any actual or reasonably suspected data breach they become aware of that may impact any of the other party's information and/or data and use best efforts to contain, remediate, and protect against the reoccurrence of such breach. Each party shall further summarize in reasonable detail the impact to the other party related to the breach and corrective actions taken and shall assist the other party in further protecting its data and responding to all inquiries or filings such party is obligated to respond to.
- g. Certification Regarding Healthcare Debarment. Each party certifies, to the best of its knowledge and belief, that it and its employees, directors and officers are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency, including but not limited to 21 U.S.C. § 335a, disqualified under 21 C.F.R. § 312.70 or § 12.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C § 1320a-7b(f)), or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program in the U.S. or pursuant to a comparable law outside the U.S. and will not during the performance of its obligations in connection with the this Agreement, employ or use the services of any person or entity that is debarred. Each party shall provide immediate written notice to the other party if, at any time prior to the execution of or during the term of this Agreement, it becomes aware of debarment or a threatened debarment. The certification in this provision is a material representation of fact upon which reliance was placed when entering into this Agreement. Notwithstanding any provision to the contrary in this Agreement, if it is later determined that either party knowingly rendered an erroneous certification or such certification becomes erroneous by reason of changed circumstances, the other party may terminate this Agreement immediately.
- h. Export Controls. Notwithstanding any other provision of this Agreement, West will not export, re-export, or transfer any products, goods, technology, or software, or cause the export, re-export, or transfer of any products, goods, technology, or software, with Customer listed as the principal party in interest or exporter, or otherwise in Customer's name, without the valid, written authorization of Customer's Export Compliance organization. Likewise, Customer will not export, re-export, or transfer any products, goods, technology, or software, or cause the export, re-export, or transfer of any products, goods, technology, or software, with West listed as the principal party in interest or exporter, or otherwise in West's name, without the valid, written authorization of West's Corporate Trade Compliance organization. In no event will either West or Customer export, re-export, or transfer any products, goods, technology, or software if doing so would cause either party or any other person to violate the U.S. Export Administration Regulations (15 C.F.R. Part 730 et seq.), the U.S. Foreign Trade Regulations (15 C.F.R. Part 30), the U.S. Foreign Trade Regulations (15 C.F.R. Part 30), any trade or economic sanctions regulations (including those administered by OFAC (31 C.F.R. Ch.V)) or any other applicable law. Customer and West each reserves the right to revoke any such export authorization at any time and for any reason.

## 12. Intellectual Property and Tooling.

- a. Intellectual Property Ownership. "Intellectual Property" means any and all intellectual and industrial property of any kind whatsoever including inventions, discoveries, technical improvements, specifications, formulations, compositions, know-how, patent applications, patents, utility models, drawings, chemical structures, designs, samples, prototypes, data, information, ideas, methods, patterns, processes, process parameters, reports of any kind or nature, documentation, trade secrets, trade dress, logos, trademarks, service marks domain names, copyrights, business or technical information, plans, software, databases, and business or technical results. As between West and Customer, all Intellectual Property made, conceived, developed, or acquired by West in connection with procuring and/or executing Customer's order shall be owned solely by West. This Agreement does not grant, expressly or impliedly, a license to or transfer of ownership of any Intellectual Property except as otherwise stated herein.
- b. Custom Tooling. West's manufacture for Customer of any custom tools and the replacement of custom tools, if applicable, shall be the subject matter of separate tooling agreements between the parties. Unless otherwise expressly agreed in writing, Customer shall be liable for the cost of all such new and replacement custom tooling and shall promptly issue a purchase order for such tooling promptly upon West's reasonable advance written notice, inclusive of details related to the custom tools involved and the cost and time estimates for maintenance, repair or replacement. In the event that Customer fails to promptly authorize the maintenance, repair or replacement of any custom tooling by issuing such purchase order: (i) West may suspend production of and/or increase pricing for the impacted Products, and (ii) Customer shall waive all claims relating, directly or indirectly, to non-conforming Product manufactured using such custom tooling to the extent such non-conformities would have been eliminated, reduced or ameliorated had the custom tooling been properly maintained, repaired or replaced per West's written notice. Custom tooling for elastomeric and metal Products (including molds and dies) designed or fabricated by West will not be returned to Customer under any circumstances. All tooling held in West's plant [\*\*\*] after completion of the most recent production order will be considered obsolete and may be disposed of by West as it deems necessary or advisable without notice to Customer. The parties agree that to the extent there is a conflict between the terms and conditions of this Agreement and a tooling agreement, the tooling agreement shall control with respect to tooling issues.

### 13. Confidentiality.

- a. **Definition.** "Confidential Information" means all confidential or proprietary information of a Disclosing Party (as defined below), documents and materials, whether printed or in machine-readable form or otherwise, including but not limited to, processes, hardware, software, inventions, ideas, designs, research, know-how, business methods, production plans, marketing plans, quantitative and qualitative formula information, and scientific, clinical, regulatory, financial and commercial information, data or results and all other proprietary and intangible rights, property and assets. Confidential Information also includes confidential or proprietary information obtained or acquired by visual observation of the Disclosing Party's (defined below) information, facilities or processes. The terms and conditions of this Agreement are the Confidential Information of each party.
- b. **West Highly Confidential Information.** From time to time in response to specific Customer requests and subject to applicable fees and terms, West may disclose, make available, or provide access to Customer via West's internet portal, certain West Highly Confidential Information, which is subject to the additional confidentiality provisions set forth in Exhibit B.

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- c. **Limitations on Use and Disclosure.** Each party (the "Receiving Party") agrees not to disclose to others or use for its own benefit except in connection with the performance of this Agreement or evaluation of a potential mutual business engagement between the parties or the benefit of others, any Confidential Information (including Intellectual Property) of the other party (the "Disclosing Party") disclosed or provided during the term of this Agreement. The Receiving Party may disclose Confidential Information to its Affiliates and to its and their directors, officers, employees, and permitted subcontractors ("Representatives") on a need-to-know basis in order to carry out their duties in connection with this Agreement; provided that such Representatives are subject to written obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use in this Section 13 (with a duration of confidentiality and non-use that is commercially reasonable under the circumstances); and provided further that the Receiving Party will be responsible for any breach of confidentiality by its Representatives. The Receiving Party shall use the same degree of care in protecting and using the Confidential Information received under this Agreement as it would use in protecting its own Confidential Information, but in no case less than a reasonable degree of care.
- d. **Exclusions.** The term Confidential Information shall not include information that: (i) is obtained by Receiving Party from a third party who (A) is rightfully in possession of the Confidential Information and (B) does not violate any obligation of confidentiality or non-use by disclosing such Confidential Information; (ii) is or becomes part of the public domain through no fault of the Receiving Party or its Representatives; (iii) was or is independently ascertained or developed by the Receiving Party or its Representatives without use of or access to Confidential Information; or (iv) is approved for disclosure and release by written authorization of the Disclosing Party. Confidential Information may be disclosed without breaching this Agreement if such Confidential Information is required to be disclosed by a court or judicial or governmental or regulatory authority of competent jurisdiction or by any applicable law, rule or regulation and, in such event, only after the Receiving Party (if not legally prohibited) provides prompt written notice to the Disclosing Party so as to enable the Disclosing Party to resist any such required disclosure and/or to obtain suitable protection regarding such required disclosure; provided that if a protective order is not obtained and the Confidential Information must be disclosed, the Receiving Party shall furnish only that portion of the Confidential Information that is required or requested and use commercially reasonable efforts to have such disclosed Confidential Information treated as confidential, including without limitation by marking the disclosed Confidential Information as "Confidential." Specific information disclosed as part of Confidential Information shall not be considered available to the general public, in the public domain, or in the prior possession of the recipient merely because it is embraced by more general information available to the general public or in the prior possession of the recipient.
- e. **Disposition; Ownership.** At the Disclosing Party's written request, the Receiving Party shall promptly return or certify the destruction of all the Disclosing Party's Confidential Information; provided, however, that the Receiving Party may retain one copy of any Confidential Information in its confidential files for archival purposes and any computer records or files containing such Confidential Information that have been created solely by the Receiving Party's automatic archiving and back-up procedures (to the extent created and retained in a manner consistent with its standard archiving and back-up procedures), which will be maintained in accordance with the confidentiality obligations of this Agreement and not used for any other purpose. All Confidential Information disclosed to, delivered to, or acquired by the Receiving Party from the Disclosing Party under this Agreement will be and remain the sole property of the Disclosing Party.

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- f. **Publicity.** Neither party shall mention or otherwise use the name, trademarks, trade names or logos of the other party (or any abbreviation or adaptation thereof) or disclose information related to the existence or terms and conditions of this Agreement in any publication, announcement, press release, promotional material or other public communication without the prior written approval of such other party ("Publication"). Each party will provide to the other party for prior review and comment any proposed Publication concerning this Agreement. The parties agree that Publications shall not contain Confidential Information of the other party and, if disclosure of Confidential Information is required by law or regulation, shall make reasonable efforts to minimize such disclosure. Each party shall have the right to review and require changes to any Publication regarding this Agreement or the subject matter of this

Agreement. Except as otherwise required by law, the party whose Publication has been reviewed shall remove or revise any information the reviewing party reasonably deems to be inappropriate for disclosure.

- g. Equitable Remedies. Each party acknowledges that remedies at law may be inadequate to protect the Disclosing Party against breach of the confidentiality obligations of this Section 13, and the parties agree in advance either party will be entitled, in addition to any monetary damages and other remedies available at law or in equity, to specific performance and injunctive relief in the event of such breach. NOTHING HEREIN SHALL LIMIT EITHER PARTY'S LIABILITY FOR BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN THIS SECTION.
  - h. Duration of Obligations. The obligations of this Section 13 will survive for a period of five (5) years from the expiration or termination of this Agreement.
14. Business Review Meetings. Customer and West shall participate in business review meetings during the Term on a periodic (but no less than annual) basis at a mutually agreed time and location, including virtually. The agenda for these meetings shall be jointly determined, but are expected to address the current and anticipated business drivers affecting each party including, without limitation, new products and new business opportunities, including without limitation Customer's current injectable pipeline molecules with associated elastomer and seal key features that have been selected, the Products that are being used on the molecule and the volume estimate of the Products to be used in the upcoming calendar year.
15. Default and Termination.
- a. Termination for Breach. Either party has the right to terminate this Agreement upon material breach by the other party upon [\*\*\*] notice if such breach is not cured within such [\*\*\*] period. Such notice will specify in reasonable detail the material breach and the basis upon which this Agreement is to be terminated. If by its nature such breach cannot be cured within such [\*\*\*] period and the breaching party is proceeding diligently to effect a cure of such breach, then this Agreement may not be terminated for an additional [\*\*\*] or until such time as the breaching party ceases to effect a cure, whichever is shorter. Notwithstanding the foregoing, Customer's failure to make payments as required by this Agreement shall not be subject to the additional cure period referred to above, and without prejudice to its other available remedies, West shall have the right to defer delivery of Product until delinquent amounts have been paid in full, revise Customer's payment terms to require payment in advance and/or terminate this Agreement immediately upon such failure to pay.
  - b. Termination for Insolvency. This Agreement may be terminated by either party on immediate written notice in the event that the other party becomes insolvent, bankrupt, makes an assignment for the benefit of creditors, or otherwise becomes subject to a plan of reorganization.

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- c. Survival. Termination or expiration of this Agreement shall not affect the rights and obligations of the parties that accrued prior to the effective date of such termination or expiration, including without limitation under any orders accepted by West prior to the effective date of such termination or expiration. Any provision of this Agreement which, by its nature or express terms, should survive termination or expiration, shall survive termination or expiration of this Agreement for any reason, including without limitation: Sections 3(d) (Cancellation), 4(a) (Payment Terms), 4(c) (Storage), 5 (Inspection), 7 (Force Majeure), 9 (Representations, Warranties, Remedies, Indemnification, and Limitations of Liability), 12 (Intellectual Property and Tooling), 13 (Confidentiality), this Section 15(c) (Survival) and Section 16 (Miscellaneous).
16. Miscellaneous.
- a. Limitation of End Usage. Customer acknowledges and agrees that Products shall be used for packaging (or administering, if applicable) medical and pharmaceutical products and not any other use without the prior written consent of West, which West may withhold in its sole and absolute discretion. Customer shall not re-sell or further distribute Products except as they are incorporated into pharmaceutical products as contemplated herein. Without prior written consent, Customer will not reverse engineer, reproduce, analyze, have analyzed, disassemble, repair or have repaired, or otherwise attempt to determine the composition, structure or manufacturing process of the Products.
  - b. Entire Agreement; Conflicting Documents. This Agreement, including the Exhibits attached hereto, which are incorporated herein by reference, constitutes the entire agreement between the parties concerning the subject matter contained in this Agreement and supersedes all written or oral prior agreements or understandings with respect thereto. This Agreement shall be deemed to be jointly prepared by the parties and neither party shall claim the benefit of any rule of interpretation, which would cause ambiguities in this Agreement to be interpreted against the party who drafted it. No course of dealing, usage of trade or course of performance will be relevant to explain or supplement any of these terms and conditions. The paragraph headings herein are for convenience only and shall not affect the meaning or interpretation of this Agreement. Customer's purchase orders with respect to Products to be purchased hereunder shall be governed solely by the terms and conditions of this Agreement, and terms or conditions contained in any purchase orders, invoices, sales receipts, shipping documents, forms, billing documents or other similar documents issued by either party hereto to the other shall be without force or effect.
  - c. Assignment. Neither this Agreement nor any of the rights hereunder may be assigned by either party hereto except with the prior written consent of the other party; provided, however, that either party may assign this Agreement to any of its Affiliates or to a successor in the event of a purchase, merger, or consolidation of all or substantially all of such party's assets (except if such merger, consolidation or sale is with a direct competitor of the other party) by providing written notice to the other party. Any purported assignment to the contrary shall be void.
  - d. Notices. All notices, requests, consents, and other communications required or permitted under this Agreement shall be in writing and shall be hand-delivered, mailed by postage prepaid registered or certified mail, return receipt requested, or sent by a guaranteed overnight delivery service, and addressed to:

**If to Customer:**

Dynavax Technologies Corporation  
2100 Powell Street, Suite 720  
Emeryville, CA 94608

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Attn: John Slebir; George Clothier

**If to West:**

West Pharmaceutical Services, Inc.  
530 Herman O. West Drive  
Exton, Pennsylvania 19341  
Attention: VP, Commercial Development

**with a copy to:**

West Pharmaceutical Services, Inc.  
530 Herman O. West Drive  
Exton, Pennsylvania 19341  
Attention: General Counsel

or to such other place and with such copies as either party may designate by notice to the other party in the manner prescribed above. All notices shall be deemed delivered upon receipt.

- e. **Taxes.** Each party shall be responsible for all taxes imposed on it by any applicable law, and unless otherwise, stated, all prices quoted by West are net, exclusive of taxes. For the sake of clarity and without limiting the generality of the foregoing, all value added, goods and services, occupational, sales, excise, use, business, stamp, withholding, service, gross income or other taxes or surcharges associated with the sale of the Products shall be paid by Customer, and all federal and state income taxes and unemployment and other employee-related taxes imposed upon West shall be paid by West. In some instances, pallet fees will be separately charged and paid by Customer. Responsibility for import and export duties shall be borne by West or Customer based upon the DAP INCOTERM applicable to the associated shipment.
- f. **Governing Law.** This Agreement and performance hereunder shall be controlled and governed exclusively in accordance with the laws of the State of Delaware (and U.S. federal law to the extent applicable), regardless of the laws governing the principles of conflicts of laws applicable thereto. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.
- g. **Jurisdiction.** The parties hereby unconditionally and irrevocably submit to (and waive any objection on the grounds of inconvenient forum or otherwise) the jurisdiction of the courts of the State of Delaware or the U.S. District Court for the located in Wilmington, Delaware, which courts shall have sole and exclusive jurisdiction to adjudicate and determine any suit, action or proceeding regarding or relating to this Agreement. A judgment, order or decision of those courts in respect of any such claim or dispute shall be conclusive and may be recognized and enforced by any courts of any state, country or other jurisdiction.
- h. **Severability.** If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.
- i. **Amendment; Waiver.** Except as otherwise expressly set forth herein, no amendment or modification to or waiver of the terms to this Agreement shall be effective unless it is in writing and executed by the parties' respective authorized representatives. Failure by either party to

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enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by a party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

- j. **Independent Contractor Status.** The relationship of West and Customer established by this Agreement is that of independent contractors, and neither party has the authority to bind the other or otherwise act in any way as the representative as the other unless otherwise expressly agreed to in a writing executed

by the parties' respective authorized representatives. Nothing contained in this Agreement shall be construed to constitute West or Customer as a partner, agent, or joint venturer with the other party or as a participant in a joint or common undertaking with the other party.

- k. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be an original but together shall constitute a single Agreement.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute this Agreement.

**DYNAVAX TECHNOLOGIES CORPORATION**

By: /s/ David Novack  
Name: David Novack  
Title: President and COO  
Date: February 10, 2025

**WEST PHARMACEUTICAL SERVICES, INC.**

By: /s/ Brett Unruh  
Name: Brett Unruh  
Title: Senior Director, Sales  
Date: February 7, 2025

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**EXHIBIT A  
PRICING EXHIBIT**

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**EXHIBIT B  
WEST HIGHLY CONFIDENTIAL INFORMATION**

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**Dynavax Technologies Corporation**  
**Insider Trading Policy**  
**(Adopted May 25, 2023)**

## Introduction

During the course of your relationship with Dynavax Technologies Corporation ("**Dynavax**"), you may receive material information that is not yet publicly available ("**material nonpublic information**") about Dynavax or other publicly traded companies that Dynavax has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, an advantage over others when deciding whether to buy, sell or otherwise transact in Dynavax's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Dynavax securities by our employees, directors and designated consultants who are advised that they are subject to this policy ("designated consultants") and the other persons subject to this policy as described below.

## Statement of Policy

It is the policy of Dynavax that an employee, director or consultant of Dynavax (or any other person subject to this policy) who is aware of material nonpublic information relating to Dynavax may not, directly or indirectly:

1. engage in any transactions in Dynavax's securities, except as otherwise specified under the heading "**Exceptions to this Policy**" below;
2. recommend the purchase or sale of any Dynavax's securities;
3. disclose material nonpublic information to persons within Dynavax whose jobs do not require them to have that information, or outside of Dynavax to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Dynavax's policies regarding the protection or authorized external disclosure of information regarding Dynavax; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies **even if** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of any material nonpublic information relating to Dynavax at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Dynavax's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is prohibited by law and is also squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Dynavax that no employee, director or consultant of Dynavax (or any other person subject to

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this policy) may either (a) recommend to another person that they buy, hold or sell Dynavax's securities **at any time** or (b) disclose material nonpublic information to persons within Dynavax whose jobs do not require them to have that information, or outside of Dynavax to other persons (unless the disclosure is made in accordance with Dynavax's policies regarding the protection or authorized external disclosure of information regarding Dynavax).

In addition, it is the policy of Dynavax that no employee, director or designated consultant of Dynavax (or any other person subject to this policy) who, in the course of working for Dynavax, learns of or is otherwise aware of material nonpublic information about another publicly traded company with which Dynavax does business, including any customer, supplier, partner or collaborator of Dynavax, may trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this policy, except as specifically noted above or below.

## Transactions Subject to This Policy

This policy applies to all transactions in securities issued by Dynavax, as well as derivative securities that are not issued by Dynavax, such as exchange-traded put or call options or swaps relating to Dynavax's securities. Accordingly, for purposes of this policy, the terms "**trade**," "**trading**" and "**transactions**" include not only purchases and sales of

Dynavax's common stock in the public market but also any other purchases, sales, transfers or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

## Persons Subject to This Policy

This policy applies to you and all other employees, directors and designated consultants of Dynavax and its subsidiaries. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund or if the fund has not implemented sufficient insider trading controls and procedures to eliminate the flow of information between you to the persons who do influence, direct or control such transactions). The foregoing persons who are deemed subject to this policy are referred to in this policy as **"Related Persons."** You are responsible for making sure that your Related Persons comply with this policy.

## Material Nonpublic Information

### Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: *whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities.* If the information makes you want to trade, or delay or avoid trading, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

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- financial results or forecasts;
- status of product or product candidate development or regulatory approvals for us or our collaborators;
- clinical data relating to products or product candidates for us or our collaborators;
- timelines for relevant pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for Dynavax's securities;
- gain or loss of a significant licensor, licensee or supplier; and
- changes or new corporate partner relationships or collaborations.
- notice of issuance or denial of patents;
- regulatory developments, whether positive or negative;
- management or control changes;
- employee layoffs;
- a disruption in Dynavax's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

### When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the **"SEC"**), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after one full trading day has elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Thursday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Friday. Depending on the particular circumstances, Dynavax may determine that a longer waiting period should apply to the release of specific material nonpublic information.

## Quarterly Trading Blackouts

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and designated consultants will possess material nonpublic information at certain points during the year. To minimize even the appearance of insider trading among our employees, directors and designated consultants, we have established "quarterly trading blackout periods" during which Dynavax employees, directors, designated consultants and their Related Persons— regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Dynavax securities. That means that, except as described in this policy, all Dynavax employees, directors, designated consultants and their Related Persons will be able to trade in Dynavax securities only during limited open trading window periods that generally will begin after one full trading day has elapsed since the public dissemination of Dynavax's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Dynavax securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "**quarterly trading blackout period**" will generally begin on the fifteenth day of the third month of each fiscal quarter and end after one full trading day has elapsed since the public dissemination of Dynavax's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief

Financial Officer or General Counsel (each, a "**Trading Compliance Officer**"), there exists undisclosed information that would make trades by Dynavax employees, directors and designated consultants inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Dynavax employee, director or designated consultant who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the General Counsel. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the General Counsel concludes that the person is not in fact aware of any material nonpublic information relating to Dynavax or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

## Event-Specific Trading Blackouts

From time to time, an event may occur that is material to Dynavax and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by a Trading Compliance Officer may not trade in Dynavax's securities. In that situation, Dynavax will notify the designated individuals that neither they nor their Related Persons may trade in the Dynavax's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

## Exceptions to This Policy

This policy does not apply in the case of the following transactions, except as specifically noted:

- 1. Option Exercises.** This policy does not apply to the exercise of options granted under Dynavax's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company or, if permitted, by delivery to Dynavax of already-owned Dynavax stock. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.
- 2. Tax Withholding Transactions.** This policy does not apply to the surrender of shares directly to Dynavax to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under Dynavax's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.
- 3. ESPP.** This policy does not apply to the purchase of stock by employees under Dynavax's Employee Stock Purchase Plan ("**ESPP**") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.
- 4. 10b5-1 Automatic Trading Programs.** Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), and as permitted by Dynavax, employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Dynavax securities based on pre-determined criteria (a "**Trading Plan**"). So long as a Trading Plan is properly established, purchases and sales of Dynavax securities pursuant to that Trading Plan are not subject to this policy. To be

properly established, an employee's, director's or consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable

10b5-1 trading plan guidelines of Dynavax. Moreover, all Trading Plans must be reviewed and approved by Dynavax before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.

**5. 401(k) Plan.** This policy does not apply to purchases of Dynavax's securities in Dynavax's 401(k) plan, if presently allowed under the current 401(k) plan design, resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This policy does apply, however, to certain elections you may make under the 401(k) plan, if allowed, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Dynavax stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Dynavax stock fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Dynavax stock fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Dynavax stock fund.

#### Special and Prohibited Transactions

**1. Inherently Speculative Transactions.** No Dynavax employee, director or designated consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to Dynavax's stock.

**2. Hedging Transactions.** Hedging or monetization transactions are transactions that can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Dynavax employee, director or designated consultant to continue to own Dynavax's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Dynavax employee, director or designated consultant may no longer have the same objectives as Dynavax's other shareholders. Therefore, Dynavax employees, directors and designated consultants are prohibited from engaging in any such transactions.

**3. Margin Accounts and Pledged Securities.** Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Dynavax's securities, Dynavax employee, director and designated consultants are prohibited from holding Company Securities in a margin account or otherwise pledging Dynavax's securities as collateral for a loan.

**4. Standing and Limit Orders.** Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Dynavax employee, director or designated consultant is in possession of material nonpublic information. Dynavax therefore discourages placing standing or limit orders on Dynavax's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

#### Pre-Clearance and Advance Notice of Transactions

In addition to the requirements above, officers, directors and other applicable members of management ("**Covered Insiders**") who have been notified that they are subject to pre-clearance requirements face a further restriction: Even during an open trading window, they may not engage in any transaction in Dynavax's securities without first obtaining pre-clearance of the transaction from a Dynavax Trading Compliance Officer, or his or her designee at least two business days in advance of the proposed transaction. The Trading Compliance Officer or his or her designee will then determine whether the transaction may proceed and, if so, will (a) provide a written pre-clearance approval and (b) assist with or direct a delegate to help comply with any required reporting requirements under Section 16(a) of the

Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. Dynavax may choose to shorten this period. Approval of a pre-clearance request should not be treated as a safe-harbor from insider trading laws. Individuals remain at all times personally responsible for their own trades and compliance with applicable laws. If a person subject to pre-clearance learns of new information after a pre-clearance is approved but before a trade is executed, they must inform the Trading Compliance Officer and submit a new request.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to a Trading Compliance Officer. Once any transaction takes place, the officer, director or applicable member of management must immediately notify the Trading Compliance Officer and any other individuals identified under the heading **"Notification of Execution of Transaction"** in Dynavax's Section 16 Compliance Program so that Dynavax may assist in any Section 16 reporting obligations.

#### **Short-Swing Trading, Control Stock and Section 16 Reports**

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are described in Dynavax's Section 16 Compliance Program, and any notices of sale required by Rule 144.

#### **Prohibition of Trading During Pension Plan or 401(K) Blackouts**

No director or executive officer of Dynavax may, directly or indirectly, purchase, sell or otherwise transfer any equity security of Dynavax (other than an exempt security) during any "blackout period" (as defined in Regulation BTR under the Exchange Act) if a director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of Dynavax's securities made pursuant to, and in compliance with, a Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; or acquisitions or dispositions of equity securities by will or the laws of descent or pursuant to a domestic relations order. Dynavax will notify each director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no director or executive officer of Dynavax should engage in any transactions in Dynavax's securities, even if believed to be exempt from Regulation BTR, without first consulting with the General Counsel.

#### **Policy's Duration**

This policy continues to apply to your transactions in Dynavax's securities or the securities of other public companies engaged in business transactions with Dynavax even after your relationship with Dynavax has ended. If you are aware of material nonpublic information when your relationship with Dynavax ends, you may not trade Dynavax's securities or the securities of other applicable companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Dynavax during a trading blackout period, then you may not trade Dynavax's securities or the securities of other applicable companies until the trading blackout period has ended.

#### **Individual Responsibility**

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Dynavax and to not engage in transactions in Dynavax's securities while aware of material nonpublic information. Each individual is responsible for making sure that he or she complies

with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading **"Persons Subject to this Policy"** above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Dynavax or any employee or director of Dynavax pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Dynavax for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

#### **Penalties**

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Dynavax, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Dynavax's General Counsel, at [legal@dynavax.com](mailto:legal@dynavax.com). Please also see Frequently Asked Questions, which are attached as **Exhibit A**.

#### **Amendments**

Dynavax is committed to continuously reviewing and updating its policies and procedures. Dynavax therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of Dynavax's policies regarding insider trading may be obtained from our web site at <https://investors.dynavax.com/corporate-governance>, or by contacting [legal@dynavax.com](mailto:legal@dynavax.com).

**Exhibit A**  
**Insider Trading Policy**  
**Frequently Asked Questions**

**1. What is insider trading?**

**A:** Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If you are aware of material nonpublic information about Dynavax or another publicly traded company that Dynavax has business relationships with and you trade in Dynavax's or such other company's securities, you have broken the law and this policy.

**2. Why is insider trading illegal?**

**A:** If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

**3. What is material nonpublic information?**

**A:** Information is material if it would influence a reasonable investor whether to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

**4. Who can be guilty of insider trading?**

**A:** Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at Dynavax. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

**5. Does Dynavax have an insider trading policy?**

**A:** Yes, the insider trading policy is included above, or available to read on our website at <https://investors.dynavax.com/corporate-governance>.

**6. What if I work in a foreign office?**

**A:** The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Dynavax director, employee or designated consultant, our policies apply to you no matter where you work.

**7. What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?**

**A:** That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and

the “tippee” might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside Dynavax, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with Dynavax’s policies regarding the protection or authorized external disclosure of information regarding Dynavax). This includes anonymous discussions on the internet about Dynavax or companies with which Dynavax does business.

**8. What if I don’t tell them the information itself; I just tell them whether they should buy or sell?**

**A:** That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell Dynavax’s common stock or any derivative security related to Dynavax’s common stock, since that could be a form of tipping.

**9. What are the sanctions if I trade on material nonpublic information or tip off someone else?**

**A:** In addition to disciplinary action by Dynavax—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

**10. What is “loss avoided”?**

**A:** If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

**11. Am I restricted from trading securities of any companies other than Dynavax, for example a customer, partner, vendor or collaborator or competitor of Dynavax?**

**A:** Possibly. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company’s securities, regardless of whether the person is directly connected with that company, except in limited circumstances. Therefore, if you have material nonpublic information about another company, you should not trade in that company’s securities. You should be particularly conscious of this restriction if, through your position at Dynavax, you sometimes obtain sensitive, material information about other companies and their business dealings with Dynavax.

**12. So if I do not trade Dynavax securities when I have material nonpublic information, and I don’t “tip” other people, I am in the clear, right?**

**A:** Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Dynavax stock as an investment, even if these actions do not violate securities laws. Our policies can be stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

**13. So when can I buy or sell my Dynavax securities?**

**A:** If you are aware of material nonpublic information, you may not buy or sell our common stock until one full trading day has elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Thursday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Friday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading “blackout” period.** Our insider trading policy describes the quarterly trading blackout period, and additional event-driven trading blackout periods may be announced by email.

**14. If I have an open order to buy or sell Dynavax securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?**

**A:** No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

**15. Am I allowed to trade derivative securities of Dynavax’s common stock?**

**A:** No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

**16. Why does Dynavax prohibit trading in derivative securities and short selling?**

**A:** Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, and short selling our common stock conflicts with our values and would not be well-received by our stockholders.

**17. Can I purchase Dynavax securities on margin or hold them in a margin account?**

**A:** Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

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**18. Why does Dynavax prohibit me from purchasing Dynavax securities on margin or holding them in a margin account?**

**A:** Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

**19. Can I pledge my Dynavax shares as collateral for a personal loan?**

**A:** No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

**20. Can I hedge my ownership position in Dynavax?**

**A:** Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own Dynavax's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as Dynavax's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

**21. Can I exercise options granted to me under Dynavax's equity compensation plans during a trading blackout period or when I possess material nonpublic information?**

**A:** Yes. You may exercise the options for cash (or via net exercise transaction with the company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information.

**22. Am I subject to trading blackout periods if I am no longer an employee or consultant of Dynavax?**

**A:** It depends. If your employment with Dynavax ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with Dynavax ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Dynavax, you should not trade in Dynavax securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

**23. Can I gift stock while I possess material nonpublic information or during a trading blackout period?**

**A:** No.

**24. What if I purchased publicly traded options or other derivative securities before I became a Dynavax employee or consultant?**

**A:** The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

**25. May I own shares of a mutual fund that invests in Dynavax?**

**A:** Yes.

**26. Are mutual fund shares holding Dynavax common stock subject to the trading blackout periods?**

**A:** No. You may trade in mutual funds holding Dynavax common stock at any time.

**27. May I use a "routine trading program" or "10b5-1 plan"?**

**A:** Subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines, eligible persons may use a routine trading program. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our legal team to confirm you are an eligible person and to obtain approval at [legal@dynavax.com](mailto:legal@dynavax.com).

**28. What happens if I violate our insider trading policy?**

**A:** Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Dynavax. In addition, you may be subject to criminal and civil sanctions.

**29. Who should I contact if I have questions about our insider trading policy or specific trades?**

**A:** You should contact our General Counsel at [legal@dynavax.com](mailto:legal@dynavax.com).

**Exhibit 21.1**

**List of Subsidiaries**

Dynavax GmbH

Dynavax India LLP

## Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3ASR Nos. 333-239663, 333-241678, and No. 333-273674) of Dynavax Technologies Corporation and in the related Prospectuses, and

(2) Registration Statements (Form S-8 Nos. 333-211747, 333-221832, 333-225525, 333-218470, 333-204506, 333-197838, 333-190313, 333-171552, 333-233247, 333-241674, 333-258469, 333-253515, 333-265373, and 333-265373) 333-281307) pertaining to the Amended and Restated 2011 Equity Incentive Plan, the Amended and Restated 2014 Employee Stock Purchase Plan, the 2017 Inducement Award Plan, the Amended and Restated 2018 Equity Incentive Plan and the 2021 Inducement Award Plan of Dynavax Technologies Corporation;

of our reports dated February 22, 2024 February 20, 2025, with respect to the consolidated financial statements of Dynavax Technologies Corporation and the effectiveness of internal control over financial reporting of Dynavax Technologies Corporation included in this Annual Report (Form 10-K) of Dynavax Technologies Corporation for the year ended December 31, 2023 December 31, 2024.

/s/ Ernst & Young LLP

San Francisco, California

February 22, 2024

20, 2025

## Rule 13a-14(a) Certification of Principal Executive Officer

## CERTIFICATIONS

I, Ryan Spencer, certify that:

1.

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

2.

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

3.

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

4.

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

- a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

I have  
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this annual  
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of Dynavax  
Technologies  
Corporation  
(the  
"registrant");  
By:

/s/ RYAN SPENCER

1.

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

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

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

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

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and  
Director

(Principal  
Executive  
Officer)

Date: February 22, 2024

February 20, 2025

Exhibit 31.2

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

CERTIFICATIONS

I, Kelly MacDonald, certify that:

1.

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

I have  
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By:

/s/ KELLY MACDONALD

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

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

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

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Refinitiv is a leading provider of financial data and analytics, serving a wide range of clients across the globe. Our commitment to innovation and excellence is reflected in our products and services, which are designed to meet the needs of our customers in a constantly evolving market. We are proud to be a part of the Refinitiv family and look forward to continuing our growth and success in the future.

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Date: February 22, 2024  
February 20, 2025

**Certification Pursuant to Section 1350 of Chapter 63**

**of Title 18 of the United States Code**

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

- (i) The Company's Annual Report on Form 10-K for the fiscal year ended **December 31, 2023** **December 31, 2024**, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set his hand hereto as of the **22<sup>nd</sup>** day of February, **2024**, **2025**.

**By:**

**By:**

/s/ RYAN SPENCER

Ryan Spencer

Chief Executive Officer and Director

(Principal Executive Officer)

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

**Exhibit 32.2**

**Certification Pursuant to Section 1350 of Chapter 63**

**of Title 18 of the United States Code**

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

- (i) The Company's Annual Report on Form 10-K for the fiscal year ended **December 31, 2023** **December 31, 2024**, to which this Certification is attached as Exhibit 32.2 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned has set her hand hereto as of the **22<sup>nd</sup>** day of February, **2024**, **2025**.

By:

By:

/s/ KELLY MACDONALD

Kelly MacDonald

Chief Financial Officer

(Principal Financial Officer)

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

Exhibit 97.1

**DYNAVAX TECHNOLOGIES CORPORATION**

**INCENTIVE COMPENSATION RECOUPMENT POLICY**

**EFFECTIVE NOVEMBER 23, 2023**

**1. INTRODUCTION**

The Board of Directors (the "**Board**") of Dynavax Technologies Corporation, a Delaware corporation (the "**Company**"), has determined, upon the recommendation of the Compensation Committee of the Board (the "**Compensation Committee**"), that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "**Policy**") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("**Rule 10D-1**") and Nasdaq Listing Rule 5608 (the "**Listing Standards**").

**2. EFFECTIVE DATE**

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "**Effective Date**"). Incentive Compensation is deemed "**received**" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

**3. DEFINITIONS**

"**Accounting Restatement**" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"**Accounting Restatement Date**" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"**Administrator**" means the Compensation Committee or, in the absence of such committee, the Board.

"**Code**" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"**Covered Officer**" means each current and former Executive Officer.

"**Exchange**" means the Nasdaq Stock Market.

**"Exchange Act"** means the U.S. Securities Exchange Act of 1934, as amended.

**"Executive Officer"** means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

**"Financial Reporting Measures"** means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("**TSR**"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

**"Incentive Compensation"** means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

**"Lookback Period"** means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

**"Recoverable Incentive Compensation"** means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (i.e., on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

**"SEC"** means the U.S. Securities and Exchange Commission.

#### 4. RECOUPMENT

(a) **Applicability of Policy.** This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv)

during the Lookback Period.

**(b) Recoupment Generally.** Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

**(c) Impracticability of Recovery.** Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

**(d) Sources of Recoupment.** To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, e.g., base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

**(e) No Indemnification of Covered Officers.** Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

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**(f) Indemnification of Administrator.** Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

**(g) No "Good Reason" for Covered Officers.** Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

## 5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out

the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. **DISCLAIMER  
SEVERABILITY**

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. **THE INFORMATION CONTAINED IN THE REFINITIV  
CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY  
BE MATERIAL ERRORS, OMISSIONS, OR  
NO IMPAIRMENT OF OTHER REMEDIES**

INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS. Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX 304") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. **AMENDMENT; TERMINATION**

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. **SUCCESSORS**

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. **REQUIRED FILINGS**

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

**INCENTIVE COMPENSATION RECOUPMENT POLICY**

**FORM OF EXECUTIVE ACKNOWLEDGMENT**

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Dynavax Technologies Corporation Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "**Policy**"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Dynavax Technologies Corporation (the "**Company**") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

**Agreed and Acknowledged:**

\_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

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