UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2025

Dynavax Technologies Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34207**	**33-0728374**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2100 Powell Street, Suite 720

Emeryville, CA	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (510) 848-5100

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 13, 2025, Dynavax Technologies Corporation ("Dynavax" or the "Company") issued a press release announcing its preliminary unaudited fourth quarter and full year 2024 financial highlights. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The preliminary selected financial results included in the press release are based upon estimates and information available as of the date of the press release. Accordingly, undue reliance should not be placed on these preliminary estimates. In addition, the Company has not yet completed its financial close process for the quarter and year ended December 31, 2024, therefore the estimates included in the press release regarding net product revenue and cash and cash equivalents, and marketable securities are preliminary, unaudited and are subject to change upon completion of the Company's financial statement closing procedures and the audit of the Company's consolidated financial statements.

Item 7.01 Regulation FD Disclosure.

The Company has posted a presentation (the "Presentation") to its website at www.dynavax.com, in the "Events & Presentations" subsection of the "News & Events" tab. A copy of the Presentation is attached as Exhibit 99.2 to this current report and is incorporated herein by reference.

All of the information furnished in this Form 8-K, including the accompanying Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this current report and in the accompanying exhibits shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Dynavax, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following exhibits are furnished herewith:

99.1	Press release dated January 13, 2025 titled "Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2024 Financial Highlights."
99.2	Dynavax Investor Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dynavax Technologies Corporation

Date: January 13, 2025

By: /s/ Kelly MacDonald

Kelly MacDonald
Senior Vice President, CFO

Exhibit 99.1

Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2024 Financial Highlights

- Preliminary 2024 HEPLISAV-B® net product revenue grew 26% year-over-year to approximately $268 million
- Enrollment completed in Phase 1/2 shingles trial; top line results expected in Q3 2025
- New $30 million contract with U.S. Department of Defense to advance plague vaccine program
- Cash, cash equivalents and marketable securities were approximately $714 million as of December 31, 2024

EMERYVILLE, CA – January 13, 2025 – Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today announced preliminary, unaudited financial highlights for the fourth quarter and full year ended December 31, 2024.

"We are excited to announce that HEPLISAV-B has achieved record annual revenue in 2024, reflecting 26% growth year-over-year, and positioning us at the upper tier of our updated guidance range. This sustained top-line growth not only underscores the strength of the HEPLISAV-B brand, but also lays a strong foundation for long-term value creation. Our robust financial position empowers us to advance our pipeline programs, maintain our focus on achieving recurring profitability, and return capital to our shareholders through an active share repurchase program," said Ryan Spencer, Chief Executive Officer of Dynavax. "Looking ahead to 2025, we are committed to executing our strategic growth pillars, which are centered on maximizing the HEPLISAV-B opportunity, delivering on our clinical pipeline, and pursuing external opportunities to generate sustainable value for our shareholders."

Business Updates and Upcoming Milestones

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

HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S., the European Union and Great Britain 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.

- HEPLISAV-B achieved preliminary net product revenue of $268 million for the full year 2024, an increase of 26% compared to $213 million for the full year 2023.
- HEPLISAV-B achieved preliminary quarterly net product revenue of $71 million for the fourth quarter of 2024, an increase of 39% compared to $51 million for the fourth quarter of 2023.
- Dynavax continues to expect the hepatitis B adult vaccine market in the U.S. to expand to a peak of over $900 million in annual sales by 2030, with HEPLISAV-B expected to achieve at least 60% total market share. Additionally, Dynavax believes 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.

The preliminary selected financial results contained herein are unaudited, subject to adjustment, and provided as an estimate in advance of the Company's announcement of complete financial results, for the three and twelve months ended December 31, 2024

Clinical Pipeline

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

HEPLISAV-B for Adults on Hemodialysis:

Dynavax is developing a four-dose HEPLISAV-B® vaccine regimen for adults on hemodialysis.

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

Shingles vaccine program:

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

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

Plague vaccine program:

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

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the plague vaccine adjuvanted with CpG 1018, Dynavax and the DoD executed a new agreement for approximately $30 million through the first half of 2027 to support additional Phase 2 clinical and manufacturing activities.

WHAT IS HEPLISAV-B?

HEPLISAV-B is a shot given to adults 18 years of age and older to help prevent infection caused by the hepatitis B virus. HEPLISAV-B is usually given in the arm muscle. HEPLISAV-B is given in 2 doses, 1 month apart, by a healthcare provider.

IMPORTANT SAFETY INFORMATION

If you have a history of severe allergic reaction after a previous dose of any hepatitis B vaccine, or to any ingredient of HEPLISAV-B, including yeast, do not take HEPLISAV-B.

HEPLISAV-B must be given by a medical professional, who will monitor you afterwards, to check for allergic reaction.

If you are immunocompromised, or receiving immunosuppressant therapy, you may have less of an immune response to HEPLISAV-B.

Some people have hepatitis B infection without being aware of it or showing any symptoms. If you already have hepatitis B present in your body, HEPLISAV-B may not prevent hepatitis B infection.

The most common side effects include pain at the injection site, tiredness, and headache.

HEPLISAV-B was not studied in pregnant or nursing women. Tell your provider if you are pregnant or plan to become pregnant or are breast feeding.

Vaccination with HEPLISAV-B may not protect all individuals.

Talk to your healthcare provider to determine if HEPLISAV-B is right for you.

For full U.S. Prescribing Information for HEPLISAV-B, please visit the following website at https://www.heplisavbhcp.com, and click the “Prescribing Information” link in the “Important Safety Information” section.

About Dynavax

Dynavax is a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S., the European Union and Great Britain for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018® adjuvant, currently used in HEPLISAV-B and multiple adjuvanted COVID-19 vaccines. For more information about our marketed products and development pipeline, visit www.dynavax.com.

Forward-Looking Statements

This press release 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. Forward-looking statements can generally be identified by the use of words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intend,” “will,” “may,” “plan,” “project,” “potential,” “seek,” “should,” “think,” “toward,” “will,” “would” and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements made in this document include statements regarding our expected financial results for the year ended December 31, 2024, expectations regarding our future growth and long-term performance, extent and timing of market growth and market share beyond 2030, the timing of IND filings, initiation and completion of clinical studies, expected timing for data readouts, and interaction with regulators. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the risk that market size or actual demand for our products may differ from our expectations, risks relating to our ability to commercialize and supply HEPLISAV-B, risks related to the timing of completion and results of current clinical studies, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the three months ended September 30, 2024 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, are qualified in their entirety by this cautionary statement and we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the U.S. Government and shall not be used for advertising or product endorsement purposes.

For Investors/Media:

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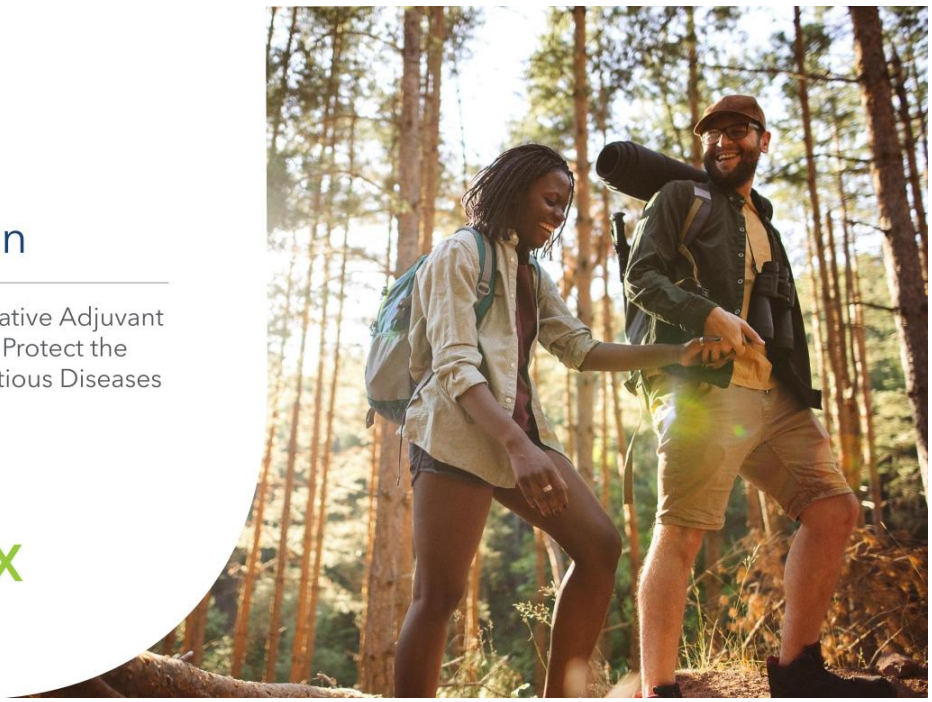
Corporate Presentation

Using Proven, Innovative Adjuvant Technology to Help Protect the World Against Infectious Diseases



DYNAVAX

January 2025
Nasdaq: DVAX

Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Dynavax's expected financial results and market share as of and for the year and quarter ended December 31, 2023, expectations regarding future growth, growth rates and market shares, expectations for vaccine markets, the company's strategic priorities, and expectations regarding the timing of IND filings, initiation and completion of clinical studies, publication of results and interaction with regulators. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks and uncertainties, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation; risks related to Dynavax's ability to successfully commercialize and supply HEPLISAV-B and grow market share, which among other things will require Dynavax to successfully negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and maintain those contractual relationships, maintain and build its commercial infrastructure, and access prescribers and other key health care providers to discuss HEPLISAV-B; risks related to market adoption and competing products; risks related to whether payors will cover and provide timely and adequate reimbursement for HEPLISAV-B; risks related to the completion, timing of completion and results of our clinical studies; and risks associated with the development, pre-clinical and clinical testing, and commercialization of vaccines in the U.S. and outside the U.S., including vaccines for COVID-19, shingles, plague and pertussis. These and other risks and uncertainties are described in Dynavax's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, or any subsequent periodic filing made by us, under the heading "Risk Factors". Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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Dynavax Core Strategic Priorities

Drive Growth in HEPLISAV-B

- Achieve at least 60% total market share by 2030
- Maximize total addressable market focused on top retailers and IDNs based on the ACIP Universal Recommendation
- Leverage foundational commercial asset to support company growth and pipeline development

Advance Differentiated Vaccine Pipeline

- Deliver on our innovative and diversified pipeline leveraging CpG 1018® adjuvant with proven antigens
- Build adult vaccine portfolio of best-in-class products
- Advance innovative pre-clinical and discovery efforts leveraging collaborations

Identify Strategic Opportunities to Accelerate Growth

- Continue disciplined allocation of capital aligned with corporate strategy to deliver long-term value through internal and external innovation
- Prioritize external opportunities with high synergy assets in vaccines, or other modalities in infectious diseases, to further leverage our expertise and capabilities

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Executing on Our Strategy: Preliminary FY 2024 Highlights[1]

Achieved record annual HEPLISAV-B net product revenue in FY'24	**HEPLISAV-B FY24 net product revenue:** $268M, up 26% YoY vs. $213M in FY23 **HEPLISAV-B Q4'24 net product revenue:** $71M, up 39% YoY vs. $51M in Q4 '23 **Long-term guidance:** Hepatitis B adult vaccine U.S. market expected to expand to a peak of over $900 million by 2030, with HEPLISAV-B expected to achieve at least 60% estimated total market share	**HEPLISAV-B total U.S. market share (as of Q3' 24):** ~44% in Q3 '24 vs. ~41% in Q3 '23
Delivering on our clinical pipeline	**HEPLISAV-B for hemodialysis:** Received FDA feedback regarding potential to conduct real-world evidence study to support sBLA on file **Shingles vaccine program:** Completed enrollment in Phase 1/2 trial; top-line results expected Q3 2025	**Plague vaccine program:** New agreement with U.S. DoD for ~$30M through 1H 2027 to fund additional Phase 2 clinical and manufacturing activities.
Achieved strong financial performance	**Cash, cash equivalents and marketable securities:** $714.0 million as of December 31, 2024	**Share repurchase plan:** In Q4'24, announced $200 million share repurchase program, including $100M Accelerated Share Repurchase

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1. Includes preliminary, unaudited financial results for FY 2024 announced on January 13, 2025

Commercial Product

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HEPLISAV-B Clinical Outcomes

Higher and faster rates of protection

HEPLISAV-B provided significantly higher rates of protection than Engerix-B **at every time point** in clinical trials

HEPLISAV-B provided significantly **higher rates of protection** in diabetics and other known hypo-responsive populations

Fewer doses

HEPLISAV-B is designed to protect with **only 2 doses in 1 month** compared to Engerix-B 3 doses in 6 months

Favorable safety profile

Across clinical trials in **nearly 10,000 participants**

Primary Endpoint Results: Study 2 per protocol population (ages 40-70)[1]

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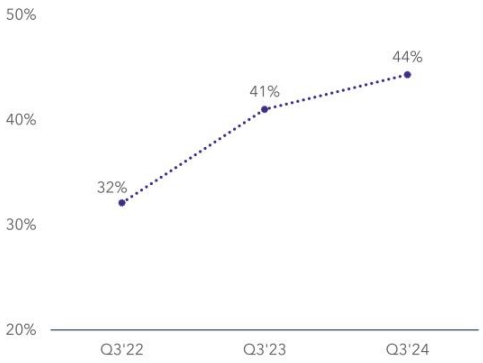
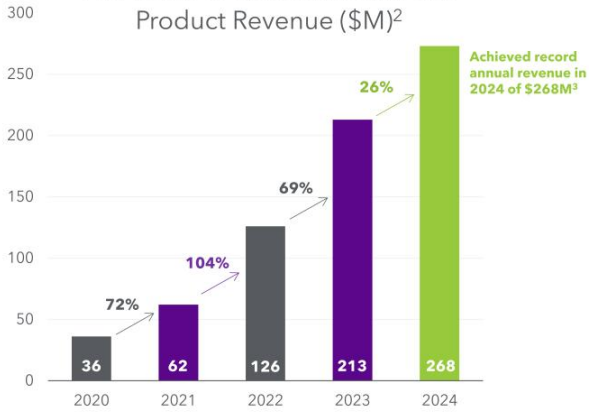
1. Dynavax Technologies Corporation. FDA Advisory Committee Briefing Document: HEPLISAV-B™ (Hepatitis B Vaccine [Recombinant], Adjuvanted). Presented at: Meeting of the Vaccines and Related Biological Products Advisory Committee; July 28, 2017; Silver Spring, MD.

Continued HEPLISAV-B Growth: Revenue & Market Share

Sequential Q3 HEPLISAV-B Vaccine Total U.S. Market Share[1]

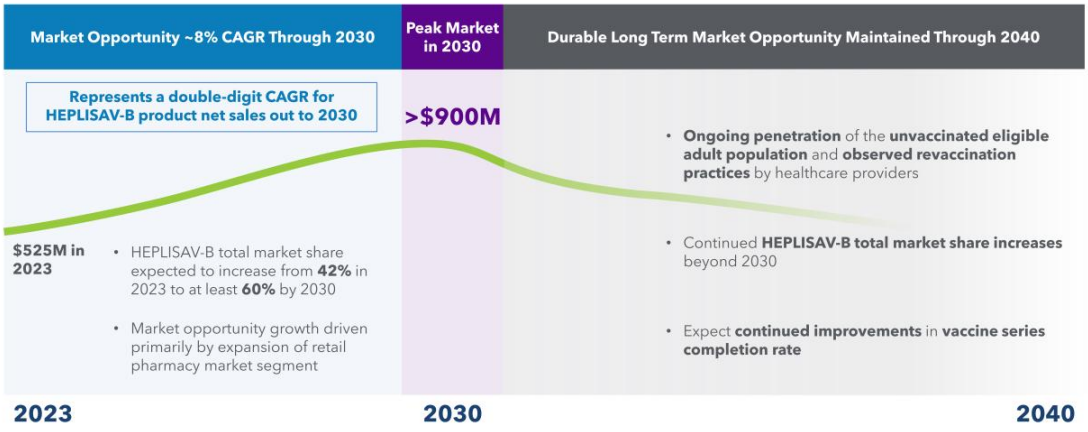


HEPLISAV-B Vaccine Annual Net Product Revenue ($M)[2]



© Copyright DYNAVAX 2025 Source: Internal data and company estimates. 1. Market share data are for Q3 of each year and do not reflect interim periods. 2. Dynavax financial reporting for fiscal years ended December 31, 2020, 2021, 2022 and 2023. 3. FY 2024 HEPLISAV-B net product revenue is preliminary and unaudited.

HEPLISAV-B Market Opportunity Expected to Grow to Over $900 M in U.S. by 2030



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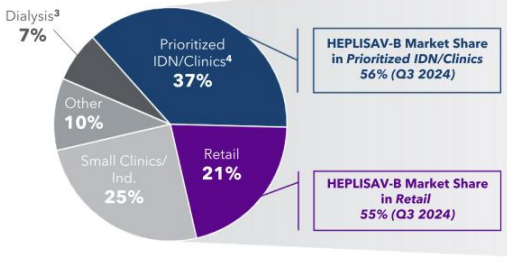
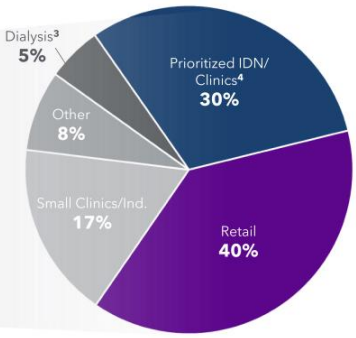
HEPLISAV-B Market Opportunity Expected to Grow to Over $900 M in U.S. by 2030

HEPLISAV-B is the market share leader in projected largest growth segments (Retail and Prioritized IDNs)

2023 Market Size: ~$525 M[1]



2030 Projected Market Size: >$900 M[2]



Source: Internal data and company estimates. Not independently verified.
1 Based on 2023 U.S. adult Hepatitis B vaccines net sales, adjusted for company estimates regarding HEPLISAV-B dosing regimen and pricing.
2 Internal estimate. Segment expansions assumes 50% of ACIP universal growth from Retail, 35% from IDN/Large Clinics and 15% from Small Clinics/Ind. No ACIP universal growth assumed in Dialysis or Other (Dept of Corrections, Occupational Health), adjusted for company estimates regarding HEPLISAV-B dosing regimen and pricing.
3 The 4-dose regimen for the dialysis population is not a currently approved regimen; safety and effectiveness have not been established in patients on hemodialysis.
4 Includes IDNs and certain large clinics which are prioritized by our salesforce

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Vaccine Development

Herpes Zoster (Shingles) | Plague

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Shingles Program: New Options Needed

Current Market-Leading Vaccine Associated with Adverse Events[1]

Herpes Zoster (shingles) is an extremely painful consequence of the reactivation of a latent varicella-zoster virus (VZV), the same virus that causes varicella (chickenpox).

Opportunity: Utilizing CpG 1018 adjuvant in a shingles vaccine may **improve vaccine tolerability while maintaining comparable efficacy** due to its ability to generate high levels of CD4+ T cell responses, which is key in controlling reactivation of the zoster virus and preventing shingles

In the U.S.: Herpes zoster rates are increasing among adults in the U.S., especially among younger adults.

Global market size: ~$4.4 B in 2023[2]

Program Status:

Recent Updates:

- Completed enrollment in Phase 1/2 trial to evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix® in 441 healthy adults aged 50 to 69.

Upcoming Milestones:

- Anticipate reporting top line immunogenicity and safety data in Q3'25, including a comparison of CD4+ T-cells one-month following the second vaccine dose.

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1. Package Insert - SHINGRIX (fda.gov) 2. Based on annual Shingrix net sales

Shingles Program: Phase 1/2 Trial Design

Top-line results expected in Q3 2025

Phase 1/2 randomized, active-controlled, dose escalation, multicenter trial of two-dose shingles vaccine Z-1018 conducted at Australian trial sites

Evaluating the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix® in 441 healthy adults aged 50 to 69

Key objectives include comparison of CD4+ T-cells

Validating a Patient Reported Outcome measurement tool to differentiate Z-1018 on reactogenicity and to support potential label claims

Optimizing Z-1018 dosing regimen:

- Dose-ranging of gE antigen
- Adjuvanted with CpG 1018® adjuvant
- Formulations with or without alum
- 2 doses with varying dosing intervals

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Plague Vaccine Program

Phase 2 program conducted in collaboration with, and funded by, the U.S. DoD

Government agencies research and stockpile medical countermeasures – biologics, drugs, devices – which may be used in the event of a potential public health emergency stemming from a biological attack or a naturally occurring emerging disease.

Opportunity: We believe incorporating CpG 1018 adjuvant with rF1V plague vaccine will **improve the durability of protection** with fewer doses administered over a shorter time period.

In the U.S.: There is **no approved vaccine**

Program Status:

Recent Updates:

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the plague vaccine adjuvanted with CpG 1018, Dynavax and the DoD executed a new agreement for ~$30 million through the 1H 2027 to support additional Phase 2 clinical and manufacturing activities.

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Financial Highlights

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Creating Value through Disciplined and Balanced Capital Allocation Strategy

Our capital allocation priorities include:

01

Maximizing HEPLISAV-B
through targeted investments

02

Investing in pipeline leveraging CpG 1018
to drive differentiated vaccine products

03

Accessing late-stage assets in infectious diseases
to further leverage our expertise and capabilities

04

Opportunistically return capital to shareholders
through share repurchase program

$200M share repurchase program authorized in November 2024

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On Track to Achieve 2024 Financial Guidance Framework (1,2)

HEPLISAV-B Performance	Operating Expenses	Driving Profitability
Net Product Revenue ✓ **$265-$270M** *Achieved $268M* Gross Margin **~80%**	R&D Operating Expense **$55-$65M** SG&A Operating Expense **$170-$180M**	Expect **positive** net income for full year 2024

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1. FY 2024 financial guidance as of Nov 7, 2024 2. Preliminary, unaudited financial results for FY 2024 announced on January 13, 2025

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- Achieve over 60% total market share by 2030
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