

# Q3 2024 Financial Results

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

**DYN**AVAX

November 2024  
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.

# Agenda

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01

## **Business Highlights**

Ryan Spencer, *Chief Executive Officer*

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## **HEPLISAV-B® Vaccine Commercial Performance**

Donn Casale, *Chief Commercial Officer*

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## **Clinical Pipeline Update**

Robert Janssen, *Chief Medical Officer*

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## **Q3 2024 Financial Results**

Kelly MacDonald, *Chief Financial Officer*

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## **Q&A Session**

# Dynavax Core Strategic Priorities



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

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## 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

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## 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

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## 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

# Executing on Our Strategy: Q3 2024 Business Highlights

## Achieved record quarterly HEPLISAV-B net product revenue in Q3'24

### HEPLISAV-B net product revenue:

\$79.3M, up 27% YoY

### HEPLISAV-B market share retail segment:

~55% vs. ~53% in Q3 '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:

~44% vs. ~41% in Q3 '23

### HEPLISAV-B market share IDN/Large Clinics segment:

~56% vs. ~54% in Q3 '23

## Optimized vaccine pipeline to focus on most promising candidates

**HEPLISAV-B regulatory updates:** Obtained FDA approval for pregnancy sBLA and FDA feedback for hemodialysis sBLA regarding potential to conduct real-world evidence study

**Shingles program:** Ongoing Phase 1/2 trial; top-line results expected 2H 2025

**Plague program:** Submitted proposal to U.S. DoD to fund additional dose optimization study and CMC work

**Tdap program:** Discontinued development due to Phase 1 extension study not demonstrating differentiated profile

## Delivered strong financial performance

**Cash, cash equivalents and marketable securities:** \$764.0 million as of September 30, 2024, compared to \$742.0 million as of December 31, 2023

**Reduced operating expense** guidance for full year 2024



## Commercial Product

# 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

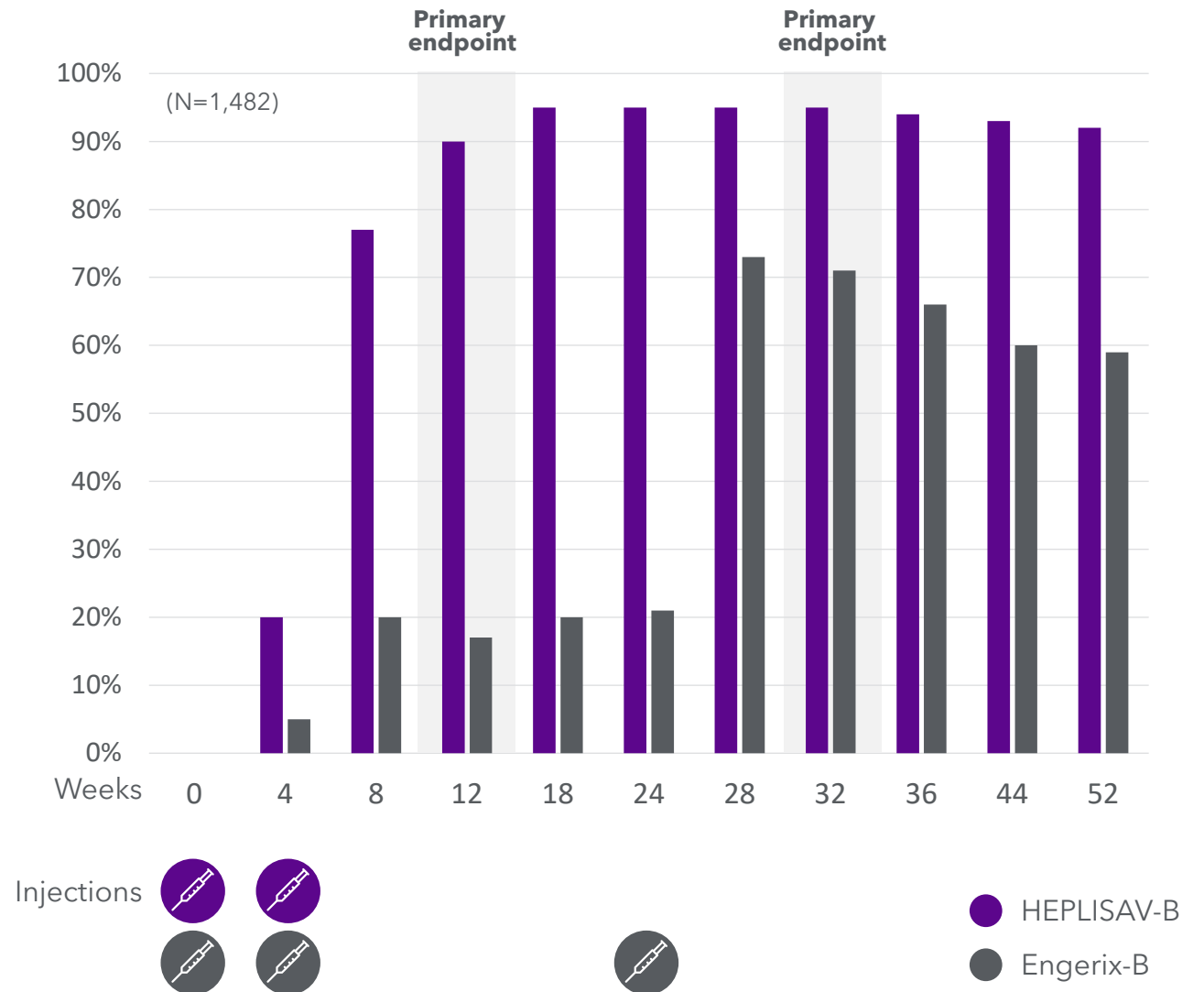
## Fewer doses

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

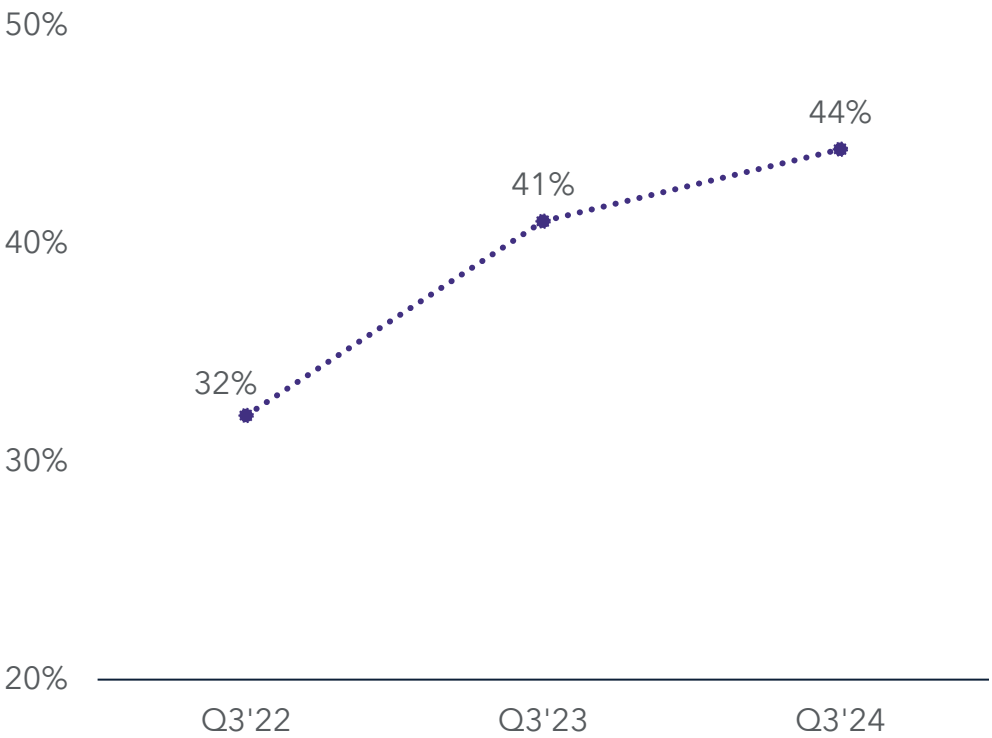
Across clinical trials in **nearly 10,000 participants**

## Primary Endpoint Results: Study 2 per protocol population (ages 40-70)<sup>1</sup>

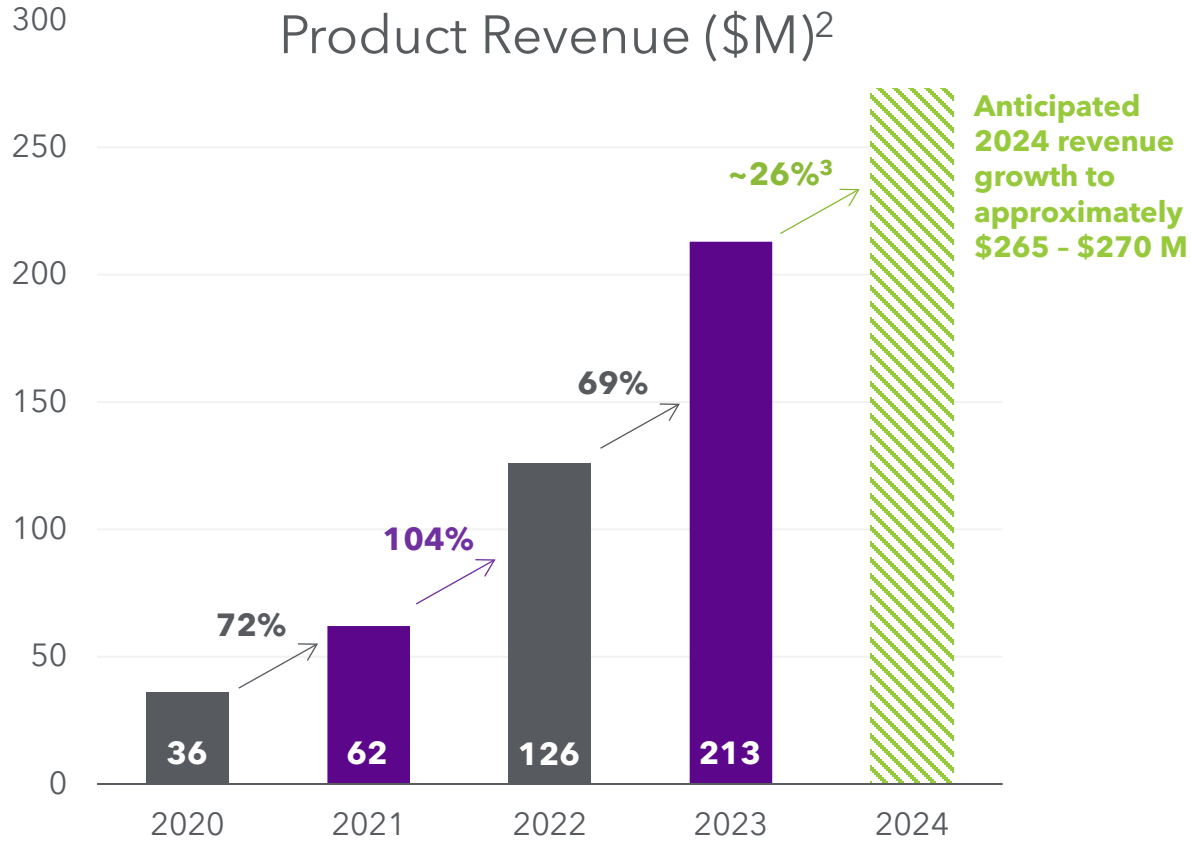


# Continued HEPLISAV-B Growth: Revenue & Market Share

Sequential Q3 HEPLISAV-B Vaccine Total U.S. Market Share<sup>1</sup>



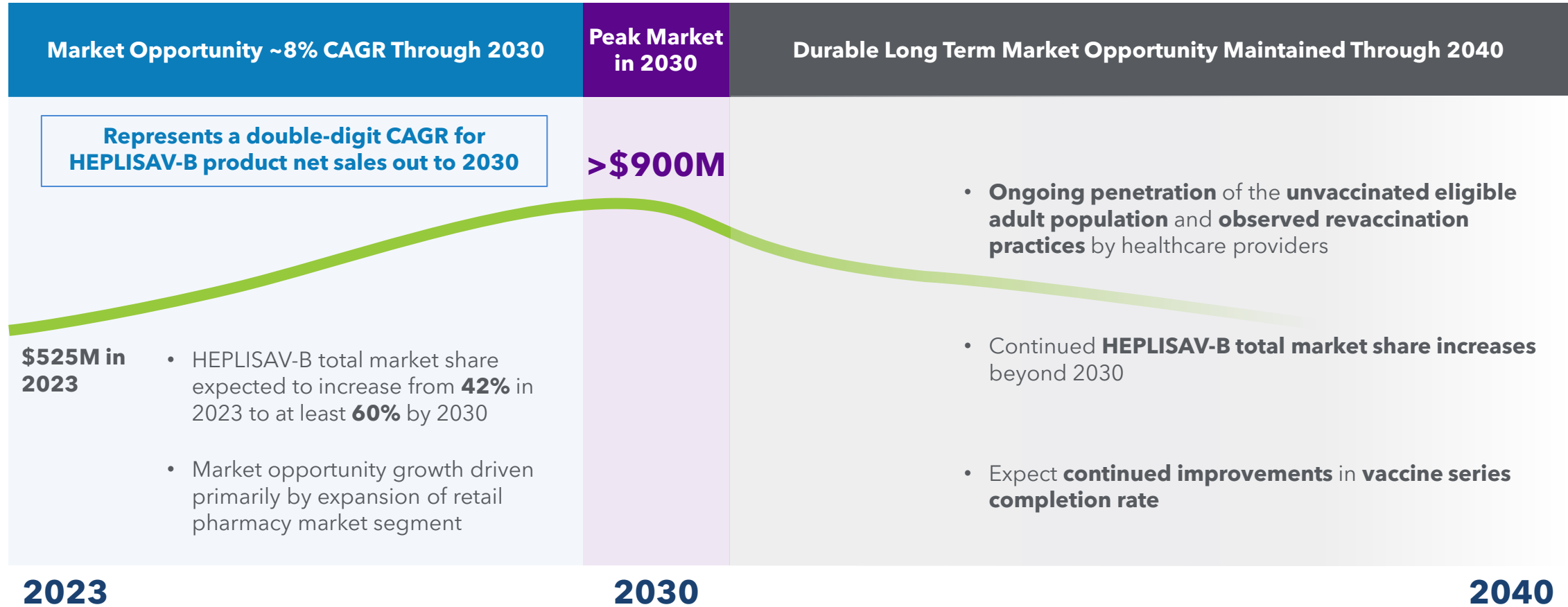
HEPLISAV-B Vaccine Annual Net Product Revenue (\$M)<sup>2</sup>



© Copyright DYNVAVAX 2024. 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 Using mid-point of guidance range for full year 2024 HEPLISAV-B net product revenue



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

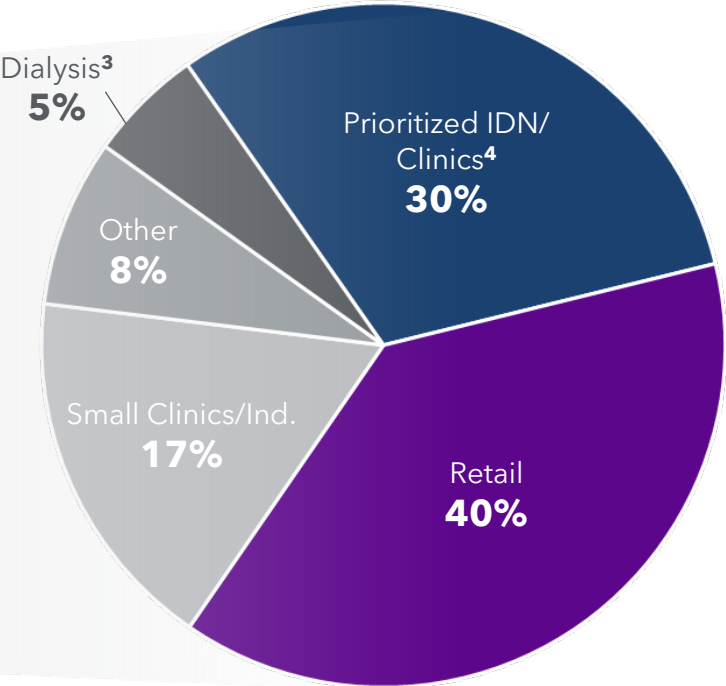
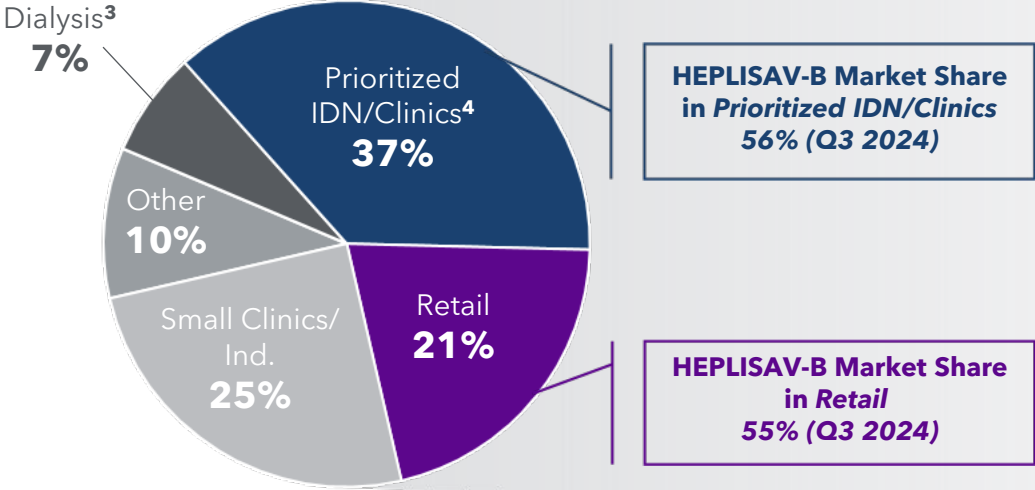


# HEPLISAV-B Market Opportunity Expected to Grow to Over \$900 M in U.S. by 2030

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

**2023 Market Size: ~\$525 M<sup>1</sup>**

**2030 Projected Market Size: >\$900 M<sup>2</sup>**



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



# Vaccine Development

Herpes Zoster (Shingles) | Plague

# Shingles Program: New Options Needed

## Current Market-Leading Vaccine Associated with Adverse Events<sup>1</sup>

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).

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**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

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

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**Global market size:** ~\$4.4 B in 2023<sup>2</sup>

### Program Status:

#### Recent Updates:

- Ongoing Phase 1/2 trial to evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix® in ~440 healthy adults aged 50 to 69.

#### Upcoming Milestones:

- Anticipates reporting top line immunogenicity and safety data in 2H25, including a comparison of CD4+ T-cells.



# Shingles Program: Phase 1/2 Trial Design

Initiated in Q3 2024

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 ~440 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

# 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.

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**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.

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

## Program Status:

### Upcoming Milestones:

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the two-dose plague vaccine adjuvanted with CpG 1018, Dynavax has submitted a proposal to the DoD regarding additional clinical and manufacturing activities.



# Financial Highlights

# Q3 2024 Financial Highlights

<b>\$80.6M</b>	<b>Total Revenues</b>	<b>Product Revenue: \$79.3M</b> <ul style="list-style-type: none"><li>HEPLISAV-B achieved record quarterly net product revenue</li><li>Increase of 27% YoY</li></ul>	<b>Other Revenue: \$1.3M</b> <ul style="list-style-type: none"><li>Reflects revenue from the plague vaccine agreement with the U.S. Department of Defense.</li></ul>
<b>\$70.5M</b>	<b>Operating Expenses</b>	<b>R&amp;D Expenses: \$14.4M</b> <ul style="list-style-type: none"><li>Increase YoY primarily driven by costs related to clinical trial activities</li></ul>	<b>S&amp;G Expenses: \$43.1M</b> <ul style="list-style-type: none"><li>Increase YoY primarily driven by increased headcount and investments to support HEPLISAV-B and pipeline growth.</li></ul>
<b>\$17.6M</b>	<b>Net Income (Loss)</b>	<b>Net Income: \$17.6M</b> <ul style="list-style-type: none"><li>Increase of 23% YoY</li></ul>	<b>Net Income per share - basic: \$0.13</b> <ul style="list-style-type: none"><li>Increase of 18% YoY</li></ul>
<b>\$764.0M</b>	<b>Cash &amp; Marketable Securities</b>	<b>Cash, cash equivalents and marketable securities: \$764.0M</b> <ul style="list-style-type: none"><li>Compared to \$742.0 million as of December 31, 2023</li></ul>	



# 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**

# On Track to Achieve 2024 Financial Guidance Framework <sup>(1)</sup>

## HEPLISAV-B Performance

Net Product Revenue  
**\$265-\$270M**

Gross Margin  
**~80%**

## Operating Expenses

R&D Operating Expense  
**\$55-\$65M**

SG&A Operating Expense  
**\$170-\$180M**

## Driving Profitability

Expect **positive** net  
income for full year 2024

*(1) 2024 financial guidance as of Nov 7, 2024*

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