



# Developing and Commercializing Innovative Vaccines

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

**DYNΛVAX**

February 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 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-K for the year ended December 31, 2023, 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.

# Dynavax at a Glance

A commercial-stage biopharmaceutical company committed to **developing and commercializing novel vaccines** to help protect the world against infectious diseases by **utilizing proven, innovative adjuvant technology**.

- **Versatile proprietary adjuvant technology**
- **Commercial vaccine with continued growth potential** and significant addressable market
- **Differentiated vaccine development pipeline** targeting large indications with unmet need
- **Fully-integrated infrastructure** supporting U.S. commercialization & global manufacturing
- **Strong financial profile**



# Dynavax Core Strategic Priorities

## Drive Growth in



- Increase market share to become the market leader by 2027
- Maximize total addressable market 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

# Executing on Our Strategy: Financial & Business Highlights

## Q4 and FY 2023 Financial Results

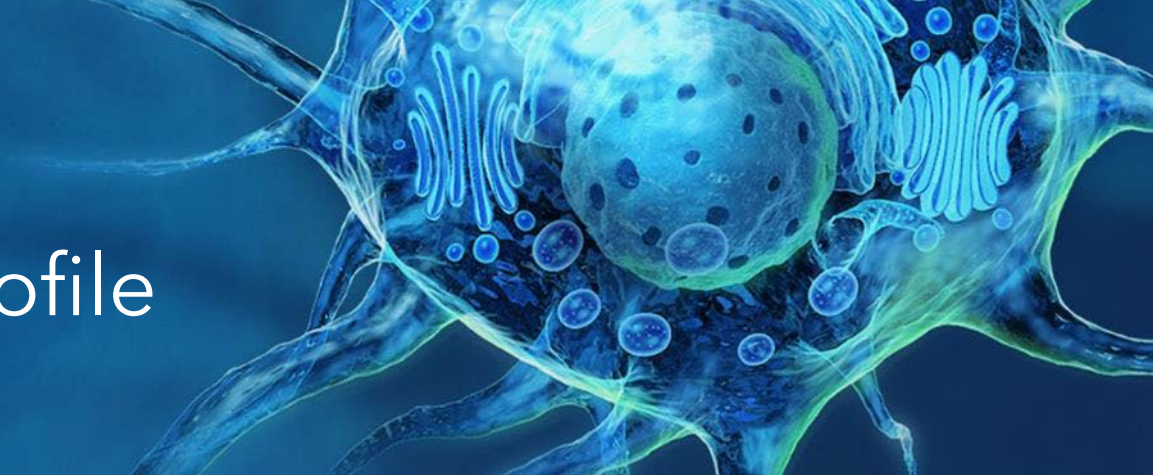
- ✓ **HEPLISAV-B®: Continued Net Revenue Growth**
  - \$51.1 M in Q4 '23 net product revenue
    - Increased ~46% year-over-year
  - \$213.3 M in FY 23 net product revenue
    - Increased ~69% year-over-year
- ✓ **HEPLISAV-B: Significant Market Share Capture**
  - ~42% in total market share compared to ~35% at end of Q4 '22
  - ~58% in retail segment share compared to ~42% at end of Q4 '22
  - ~56% in IDN/Large Clinics segment share compared to ~47% at end of Q4 '22
- ✓ **Strengthened Financial Profile**
  - \$742 M in cash, cash equivalents and marketable securities as of December 31, 2023
    - Compared to \$624 M at end of FY 2022

## Pipeline Advancement

- ✓ **HEPLISAV-B sBLA in Hemodialysis:**
  - sBLA under review by FDA with PDUFA action date expected in May 2024.
- ✓ **Shingles Program:**
  - Submitted IND to support the initiation of a Phase 1/2 trial.
- ✓ **Tdap Program:**
  - Plan to submit an IND to the U.S. FDA to support initiation of a Phase 2 human challenge study.
- ✓ **Plague Program:**
  - Executed contract modification to support advancement into a nonhuman primate challenge study, which was initiated in August.



# CpG 1018® Adjuvant: Well-defined MOA and Clinical Profile



Proprietary CpG 1018 adjuvant selectively and optimally activates TLR9 – an important toll-like receptor that elicits the body's innate immune response when invading pathogens are introduced.

## Mechanism of Action

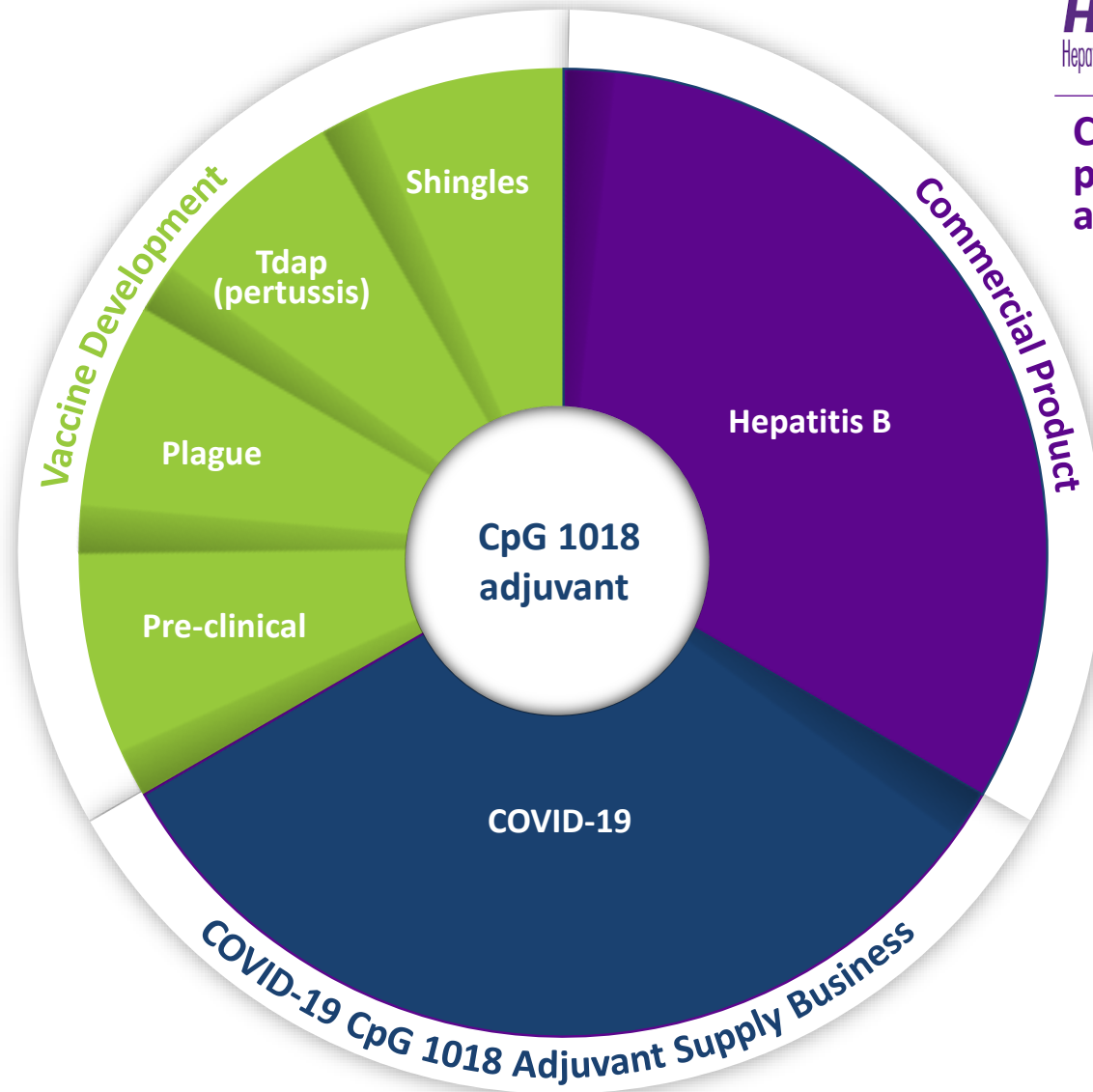
- CpG 1018 adjuvant is a synthetic form of DNA that mimics bacterial and viral DNA from infection
- TLR9 expressed primarily by plasmacytoid dendritic cells
- Elicits a T Helper (Th1) polarized CD4 T-cell response and increases antibody production

## Clinically Proven Profile

- Faster and consistently higher rates of protection in HEPLISAV-B, including in the elderly and populations less responsive to other vaccines
- Favorable tolerability profile
- Well-established safety, immunogenicity and efficacy profile as demonstrated in clinical trials (including multiple COVID-19) and commercial use (HEPLISAV-B®)

# A Broad Vaccine Platform With High Potential

Our proprietary CpG 1018 adjuvant is being used to support worldwide vaccine development for infectious diseases which take an increasing toll on public health.



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

**CpG 1018 adjuvant  
powers our FDA  
approved vaccine**

# Diversified Pipeline Leveraging CpG 1018 Adjuvant

## Commercial Products

Hepatitis B



Wholly owned by Dynavax

## Vaccine Development

Shingles



Wholly owned by Dynavax

Tdap



Serum Institute of India  
US, EU and private market commercial  
rights owned by Dynavax

Plague



U.S. Department of Defense

**COVID-19 CpG 1018 Adjuvant  
Supply Agreements\***  
(partner-developed products)



*Product Developer  
(Emergency Use Authorization):*  
BioFarma, Biological E,  
Clover Biopharmaceuticals, Medigen  
and Valneva

<sup>1</sup> Approved: U.S. commercial launch Q1-2018; EU commercial launch Q2-2022.  
<sup>2</sup> Commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany.  
\*The information provided in this section was last updated February 22, 2024; please visit partner websites for more information.





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

# Commercial Product

# There is No Cure for Hepatitis B - Prevention is Essential

Hepatitis B is an incurable liver infection caused by the hepatitis B virus transmitted by bodily fluids. When the virus attacks the liver, the resulting health complications can be lifelong or even deadly.

## Globally<sup>1</sup>

# 1 out of 3 people

have been infected with hep B (2 billion people)

**~1.5 million**

people become newly  
infected each year

**~300 million**

people living with hepatitis B

## Hepatitis B is

**100x**

more infectious than HIV

**7 days**

virus can survive outside  
the body on surfaces

**~80%**

of people are unaware of  
their infection, increasing risk  
of unknowingly spreading it  
to others

**30-59 years**

age range where new infections  
are highest

# 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

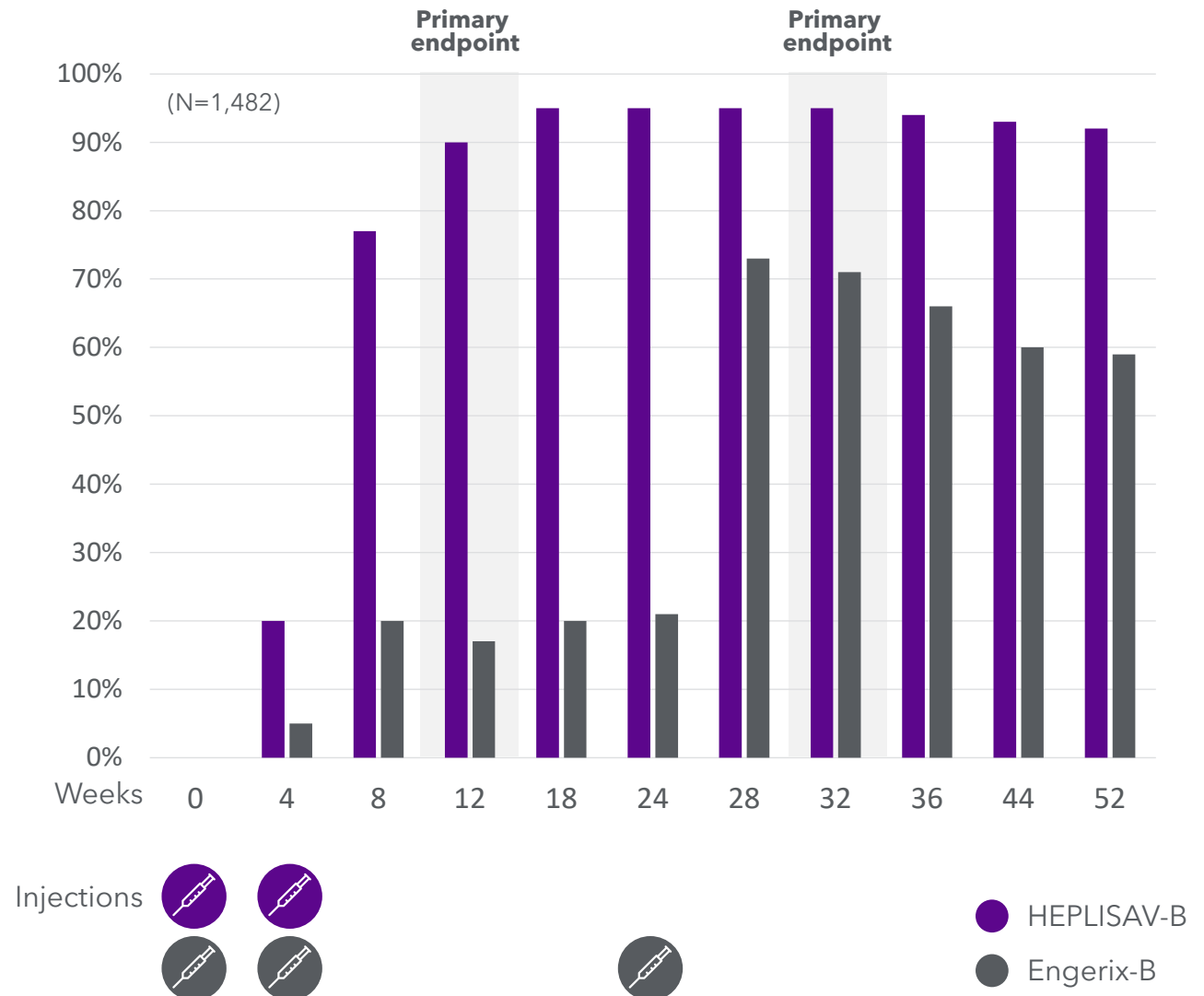
## Fewer doses

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**

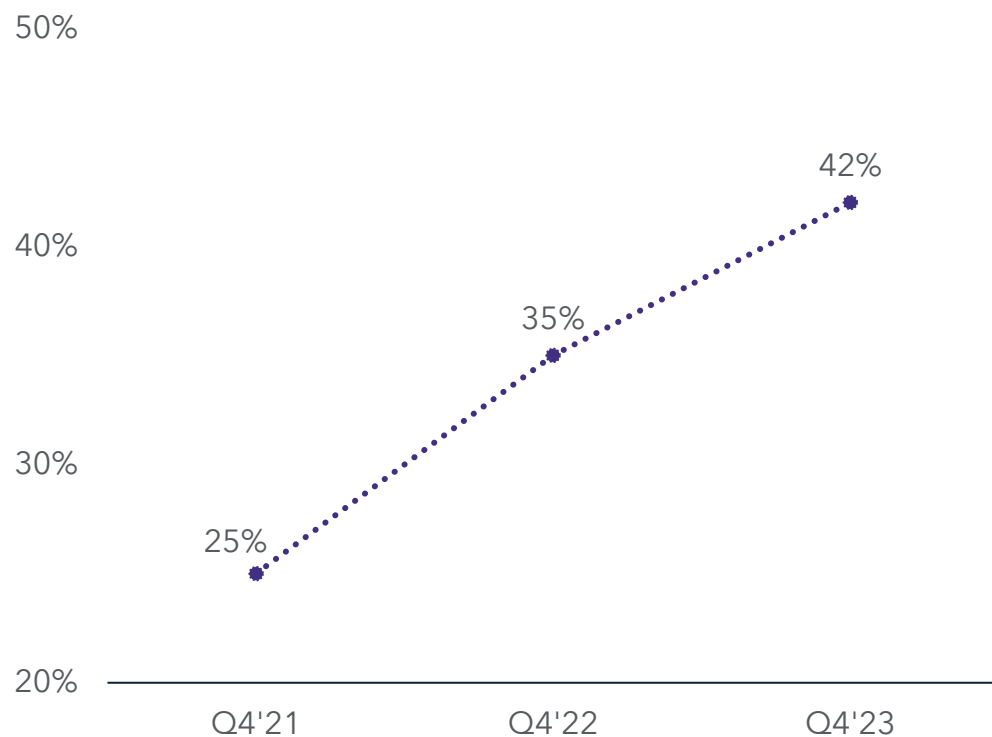
## Primary Endpoint Results: Study 2 per protocol population (ages 40-70)<sup>1</sup>



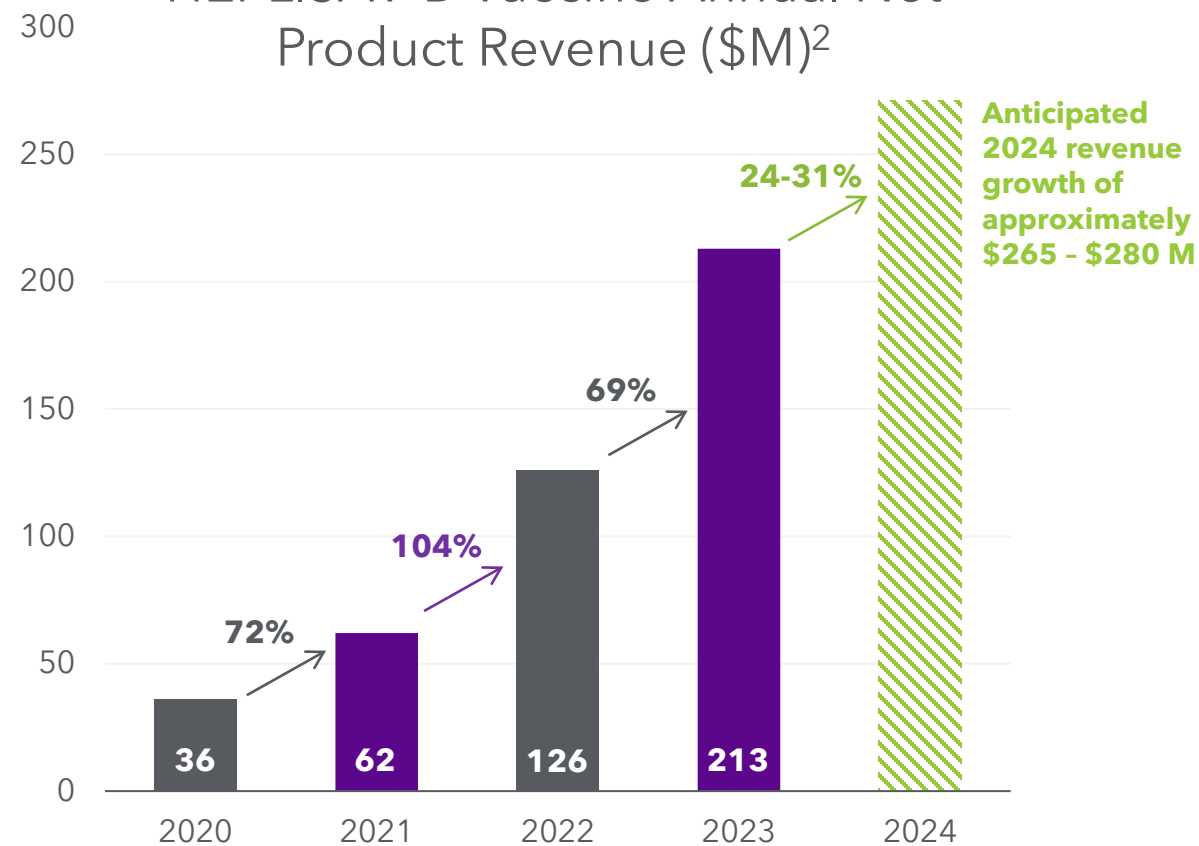


# Continued HEPLISAV-B Growth: Revenue & Market Share

## Sequential Q4 HEPLISAV-B Vaccine Total Market Share<sup>1</sup>



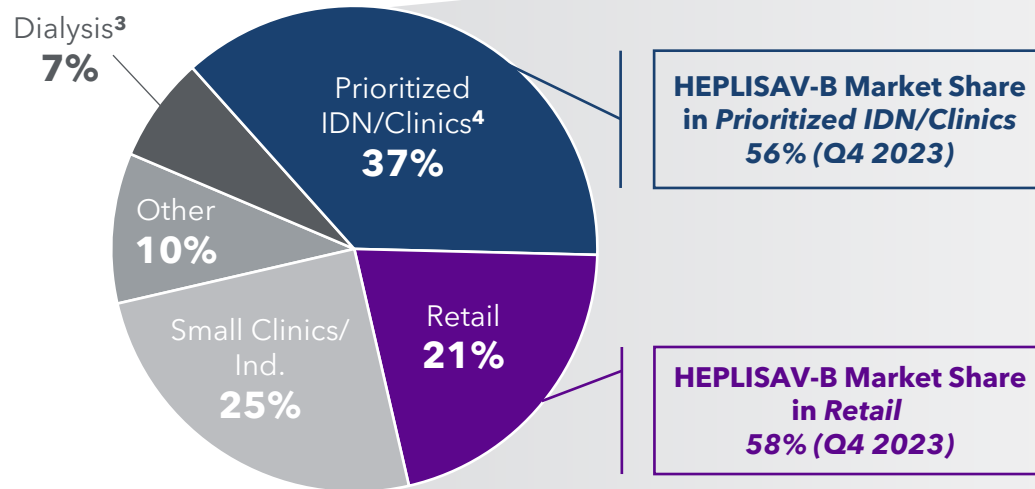
## HEPLISAV-B Vaccine Annual Net Product Revenue (\$M)<sup>2</sup>



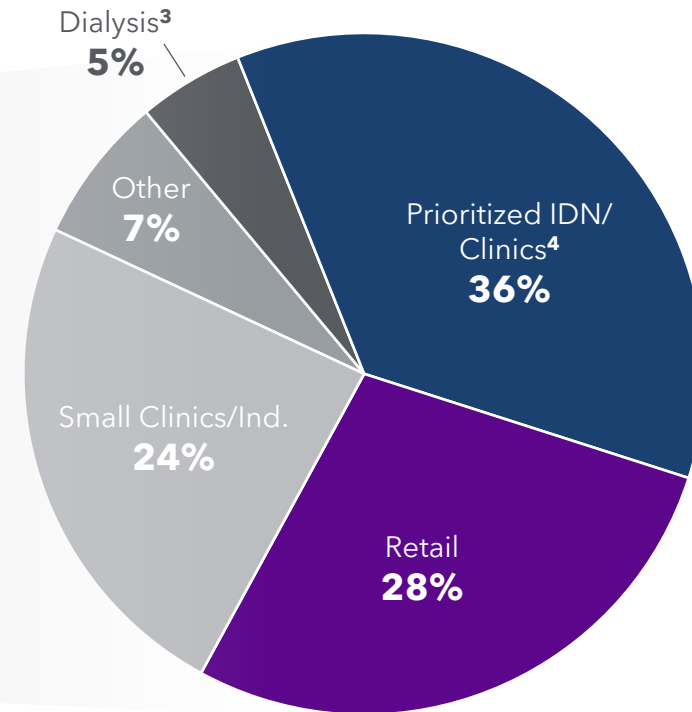
# HEPLISAV-B Market Opportunity Expected to Grow to ~\$800 M in U.S. by 2027

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

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



## 2027 Projected Market Size: ~\$800 M<sup>2</sup>



Source: Internal data and company estimates. Not independently verified.

<sup>1</sup> Based on 2023 U.S. adult Hepatitis B vaccines net sales, adjusted for company estimates regarding HEPLISAV-B dosing regimen and pricing.

<sup>2</sup> 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.

<sup>3</sup> The 4-dose regimen for the dialysis population is not currently approved regimen; safety and effectiveness have not been established in patients on hemodialysis. 13 |

<sup>4</sup> Includes IDNs and certain large clinics which are prioritized by our salesforce



# Vaccine Development

Herpes Zoster (Shingles) | Tetanus, Diphtheria, and Pertussis (Tdap) | 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:

- Phase 1 study results presented at the 2023 ACVR meeting in June 2023.
- Dynavax recently received Type B meeting feedback from the U.S. FDA on the Z-1018 clinical development plan.

#### Upcoming Milestones:

- Submitted IND to FDA to support the initiation of a Phase 1/2 trial of Z-1018 in 1H 2024.

# Tdap Vaccine Program (tetanus, diphtheria, and pertussis)

## Intended for booster immunization against Tdap

Since 1991, when acellular pertussis vaccines replaced whole-cell vaccines, whooping cough cases have increased by 85% due to:

**Waning efficacy:** Effectiveness decreases 40-60% four years post vaccination<sup>1</sup>

**Asymptomatic transmission:** current acellular vaccines do not prevent asymptomatic infection or transmission<sup>2</sup>

**Opportunity:** Utilizing CpG 1018 adjuvant is expected to **improve the durability of protection against pertussis** by redirecting T cell responses and enhancing protective antibody responses in a booster vaccine.

**In the U.S.:** Tetanus and diphtheria are rare, but pertussis continues to spread.<sup>3</sup>

**Global market size:** ~\$1.2B in 2022<sup>4</sup>

### Program Status:

#### Recent Updates:

- Pertussis challenge study in nonhuman primates (NHP) demonstrated protection from disease and robust Type 1 T helper (Th1) cell responses upon challenge in NHPs vaccinated with Tdap-1018.
- Dynavax recently received Type B meeting feedback from the FDA on the Tdap-1018 clinical development plan.

#### Upcoming Milestones:

- Plans to submit an IND to the U.S. FDA to support initiation of a Phase 2 human challenge study in 2H 2024, upon completion of the independent study conducted by the Canadian Center for Vaccinology to establish the human challenge dose.

# 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** in the U.S.

## Program Status:

### Recent Updates:

- Contract modification with U.S. DoD to support advancement into NHP challenge study, agreement now totaling \$33.7 million through 2025.
- NHP challenge study was initiated in August 2023.

### Upcoming Milestones:

- Top line data expected in 2024 for Phase 2 clinical trial and NHP challenge study.





# Propelling Future Growth

# Strong Financial Profile

*Cash Position Increased to \$742 M at Year End 2023*

<b>Annual Financial Highlights</b> (\$ millions, except per share amounts)	<b>FY 2023</b> Ended 12/31/23	<b>FY 2022</b> Ended 12/31/22	<b>% Change</b> (FY '23 vs. FY '22)
<b>Total Revenues</b>	\$232.3	\$722.7	(68%)
HEPLISAV-B vaccine net product revenue	\$213.3	\$125.9	69%
CpG 1018 adjuvant net product revenue	\$0.0	\$587.7	(100%)
Other revenue	\$19.0	\$9.0	110%
<b>Total Operating Expenses</b>			
Cost of sales - product	\$50.2	\$262.2	(81%)
Research and development expenses	\$54.9	\$46.6	18%
Selling, general & administrative expenses	\$153.0	\$131.4	16%
<b>Net Income (Loss)</b>	\$(6.4)	\$293.2	(102%)
<b>Net Income per share - basic</b>	\$(0.05)	\$2.32	(102%)
Cash, cash equivalents and marketable securities	\$742.3	\$624.4	

# Full Year 2024 Financial Guidance<sup>(1)</sup>

Dynavax expects:	FY 2024 Guidance
HEPLISAV-B Net Product Revenue	<b>\$265 - \$280 M</b>
HEPLISAV-B Gross Margin	<b>~80%</b>
Research & Development Operating Expenses <sup>(2)</sup>	<b>\$60 - \$75 M</b>
Selling, General & Administrative Operating Expenses	<b>\$160 - \$180 M</b>
Expect to be cash flow positive for full year ended December 31, 2024	

*(1) 2024 financial guidance as of February 22, 2024*

*(2) Research and development expenses expected to advance our pipeline and associated clinical trial costs for shingles, Tdap, and plague adjuvanted vaccine programs*



# Delivering on Dynavax's Value Proposition

## Building on Key Recent Accomplishments

- ✓ **HEPLISAV-B:** net product revenue of \$213 M in 2023 (69% Y/Y growth)
- ✓ **Shingles and Tdap programs:** data and regulatory feedback support continued development
- ✓ **Plague program:** expanded contract with U.S. Department of Defense
- ✓ **Strong capital position** of \$742 M in cash, cash equivalents and marketable securities at year end 2023

## 2024 Expectations

**HEPLISAV-B continued revenue growth,** and expansion of U.S. hepatitis B vaccine market share

**Advance innovative vaccine pipeline,** including regulatory and clinical activities across pipeline programs

**Identify and pursue strategic opportunities** to accelerate growth