# 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 09, 2023**

# 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**<br>**Emeryville, California** | **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 | The NASDAQ Stock Market LLC |

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 9, 2023, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its preliminary unaudited fourth quarter and full year 2022 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, 2022, 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 press release issued by the Company on January 9, 2023, and attached as Exhibit 99.1 to this current report also reported phase 1 shingles topline results.

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 exhibit 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 exhibit is furnished herewith:

| | |
|---|---|
| 99.1 | Press release dated January 9, 2023 titled "Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2022 Financial Highlights and Phase 1 Shingles Topline Results". |
| 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 9, 2023

By: /s/ Kelly MacDonald
Kelly MacDonald
Senior Vice President, CFO

DYNAVAX Exhibit 99.1

# Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2022 Financial Highlights and Phase 1 Shingles Topline Results

- **Preliminary full year 2022 HEPLISAV-B® vaccine Net Product Revenue of approximately $126 million, representing 104% growth compared to 2021**
- **Preliminary full year CpG 1018® adjuvant Net Product Revenue of approximately $588 million**
- **Maintained strong financial position with year-end cash and investments of approximately $624 million**
- **Phase 1 shingles trial results demonstrate favorable tolerability with similar vaccine response rates in CpG 1018 adjuvanted arms versus comparator vaccine**

**EMERYVILLE, CA – January 9, 2023** – Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative vaccines, today announced preliminary, unaudited financial highlights for the fourth quarter and full year ending December 31, 2022 and Phase 1 shingles topline results.

"We are pleased with the relentless execution of our strategy throughout 2022, delivering transformative progress across our commercial and development portfolio including revenue at the top end of our guidance, achievement of all of our stated clinical milestones and the strengthening of our balance sheet," said Ryan Spencer, Chief Executive Officer of Dynavax. "In 2023, we anticipate building on the strong foundation laid in 2022, with continued product revenue growth for HEPLISAV-B, advancement of our clinical development pipeline leveraging our versatile CpG 1018 adjuvant technology and execution of our corporate development objectives to help drive long-term value."

**2022 Preliminary Unaudited Commercial and Financial Highlights:**

- Preliminary HEPLISAV-B Net Product Revenue for the fourth quarter and full year 2022 were approximately $35 million and $126 million, respectively, representing quarterly and annual growth of 105% and 104% compared to Q4 2021 and full year 2021, respectively.
- Preliminary CpG 1018 adjuvant Net Product Revenue for the fourth quarter and full year 2022 were approximately $147 million and $588 million, respectively, representing the successful completion of all pandemic adjuvant delivery obligations under existing commercial supply agreements.
- Approximately $624 million in estimated Cash and Cash Equivalents, and Marketable Securities as of December 31, 2022.

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, 2022.

**Phase 1 Topline Results from Shingles Program**

The Phase 1 clinical trial (DV2-ZOS-01) was designed to evaluate an investigational shingles vaccine Z-1018, utilizing different regimens of CpG 1018 adjuvant, with or without aluminum hydroxide (alum). The trial compared Z-1018 arms versus the active comparator Shingrix®. The Company reported the following topline results, assessed at Week 12, and plans to submit an abstract for presentation at an upcoming medical meeting in the first half of 2023.

- Z-1018 demonstrated high antibody and CD4 positive T-cell vaccine response rates in all arms, which were similar to the comparator;
- Robust increases in CD4 positive T-cells were observed in all Z-1018 arms, although lower than the comparator;
- Total frequency of solicited systemic adverse events and local post-injection reactions were similar across the Z-1018 arms and lower than the comparator,
    - The frequency of moderate and severe local post-injection reactions was 9% for Z-1018 arms compared to 37% for the comparator and the frequency of moderate and severe solicited systemic adverse events was 26% for Z-1018 arms and 43% for the comparator.

“With these promising data, we have a better understanding of the potential for a CpG 1018 adjuvanted shingles vaccine to reduce post-injection reactions to improve patients’ experience compared with the currently commercialized shingles vaccine,” said Dr. Robert Janssen, Chief Medical Officer of Dynavax. “With the high vaccine response rate, and in comparison with immunologic and efficacy data from previous shingles vaccine studies, we believe our vaccine candidate has the potential to be highly efficacious.”

Based on these initial data, the Company intends to advance its shingles vaccine candidate with CpG 1018 adjuvant into a Phase 1-2 study in early 2024 to expand on these results and to evaluate various dose levels of Dynavax-manufactured gE protein.

**About DV2-ZOS-01 Clinical Trial**

DV2-ZOS-01 is a randomized, active-controlled, dose-escalation, multi-center Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of investigational herpes zoster (shingles) vaccine utilizing a commercially available gE plus CpG 1018 adjuvant (Z-1018) with and without alum compared to Shingrix® in approximately 150 healthy volunteers between the ages of 50 and 69 years of age.

For additional information about this trial, please visit www.clinicaltrials.gov using the identifier NCT05245838.

**Shingrix® is a registered trademark of GlaxoSmithKline, PLC.**

**About HEPLISAV-B**

**Important U.S. Product Information**
HEPLISAV-B is indicated for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

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.

**Important U.S. Safety Information (ISI)**
Do not administer HEPLISAV-B to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%), and headache (8% to 17%).
Dynavax

**About Dynavax**

Dynavax (Nasdaq: DVAX) 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. and the European Union 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 multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, seasonal influenza, universal influenza, plague, shingles and Tdap. For more information, visit www.dynavax.com and follow the company on LinkedIn.

**Forward Looking Statements**

This press release contains "forward-looking" statements, including statements regarding expected or anticipated financial performance, including market share, revenue and profitability, potential U.S. market for hepatitis vaccines, establishing CpG 1018 as a leading adjuvant, future sales of CpG 1018 or HEPLISAV-B or other product candidates, anticipated timing and progress of the DV2-ZOS-01 clinical trial and related data analysis, data preparation and publication, the timing of a Phase 1/2 trial for the shingles vaccine candidate or other candidates. 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 HEPLISAV-B may not become the standard of care adult hepatitis B vaccine in the U.S., risks related to whether and when prescribers and other key decision-makers at potential purchasing entities will make the decision to switch to HEPLISAV-B, and the timing and quantity of actual purchases, risks related to the timing and impact of the ACIP universal hepatitis B recommendation, risks related to the timing of completion and results of current clinical studies conducted by us or our collaborators, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, and whether use of CpG 1018 adjuvant will prove to be beneficial in these vaccine candidates, risks related to whether, risks related to the use of contract manufacturers to timely supply CpG 1018 adjuvant and financial commitments made to them, as well as other risks detailed in the "Risk Factors" and “Management’s Discussion of Financial Condition and Results of Operations” sections of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 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. We undertake 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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510-665-7264

Derek Cole, President
Investor Relations Advisory Solutions
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Exhibit 99.2

# Developing and Commercializing Innovative Vaccines

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

January 2023
Nasdaq: DVAX

DYNAVAX

# 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 the potential for HEPLISAV-B to become the market leader and standard of care in the U.S., potential market opportunity for HEPLISAV-B in the U.S., Germany and other countries in total and by segment, possible timing and impact of ACIP recommendations, timing of our clinical trial completion and data readouts, potential markets and market size for each of our products or product candidates including our shingles and Tdap candidates, catalysts for our business and their anticipated effects, development and commercialization of a vaccine for COVID-19 by one or more of our collaborators, our development and commercialization of an improved pertussis and shingles vaccine and other vaccines using our CpG 1018® adjuvant, establishing CpG 1018 as a leading adjuvant platform, potential for CpG 1018 adjuvant to speed up protection in an improved plague vaccine and future revenue potential for CpG 1018 adjuvant. 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 the continuing impact of COVID-19 on vaccine utilization and sales, including for HEPLISAV-B; risks related to the potential adverse effects of the coronavirus pandemic on our ability to access customers and on customer decision making, adoption and implementation; risks related to Dynavax's ability to successfully commercialize HEPLISAV-B, 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 post-marketing clinical trials of HEPLISAV-B, trials for other product candidates of ours or of our collaborators; risks related to development and commercialization of HEPLISAV-B in Europe and other countries; and risks associated with the development and commercialization of vaccines in the U.S. and outside the U.S., including vaccines for COVID-19, flu, shingles 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, 2022, 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 HEPLISAV-B™ Hepatitis B Vaccine (Recombinant), Adjuvanted

- Increase market share to become the market leader by 2027
- Maximize total addressable market based on the ACIP Universal Recommendation
- 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
- Pursue external opportunities to further leverage our U.S. commercial vaccine capabilities, prioritizing first or best-in-class assets

# Executing on Our Strategy: FY-2022 Preliminary* Unaudited Financial & Pipeline Highlights

## Preliminary* FY-2022 Financial Results

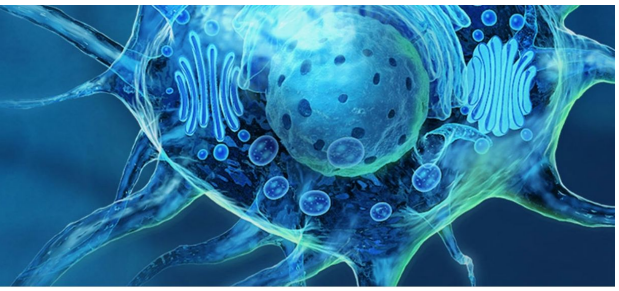
- **HEPLISAV-B®** ~104% year-over-year topline growth with ~36% in total market share exiting 2022
  ~$126 million in preliminary* FY-2022 net product revenue
- **CpG 1018® Adjuvant** supply business generated from five COVID-19 pandemic commercial supply agreements
  ~$588 million in preliminary* FY-2022 net product revenue
- **Strengthened Financial Profile**
  ~$624 million in preliminary* cash and cash equivalents, and marketable securities as of December 31, 2022

## Pipeline Execution

- **Tdap Phase 1 completed**; positive data presented in October 2022
- **Shingles Phase 1 initiated and completed**; positive topline results reported in January 2023
- **Plague Phase 2 trial initiated** in August 2022 (fully funded by the Department of Defense)

**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, 2022. These estimates represent management's expectations as of the date of posting.*

# 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

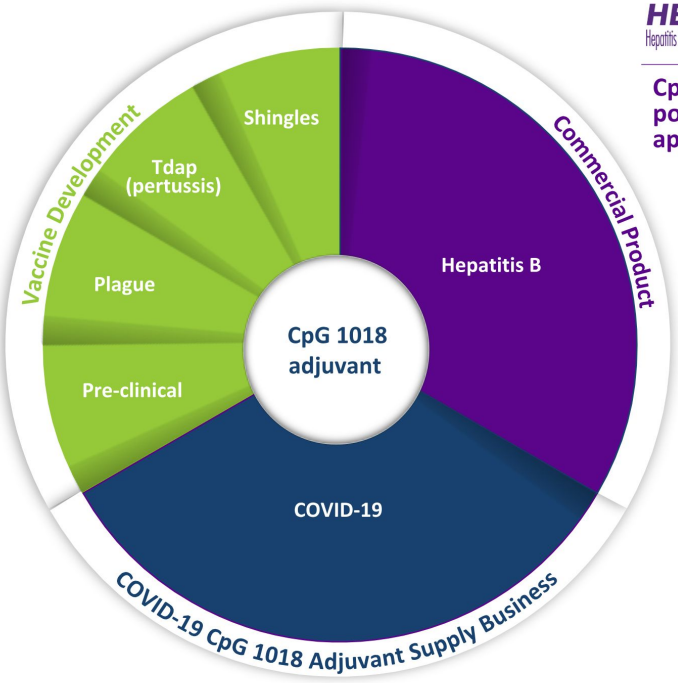
- CpG 1018 adjuvant is a synthetic form of DNA that mimics bacterial and viral DNA from infection
- TLR9 expressed primarily by plasmacytoid dendritic cells
- Elicits a T Helper (Th1) polarized CD4 T-cell response and increases antibody production

## 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

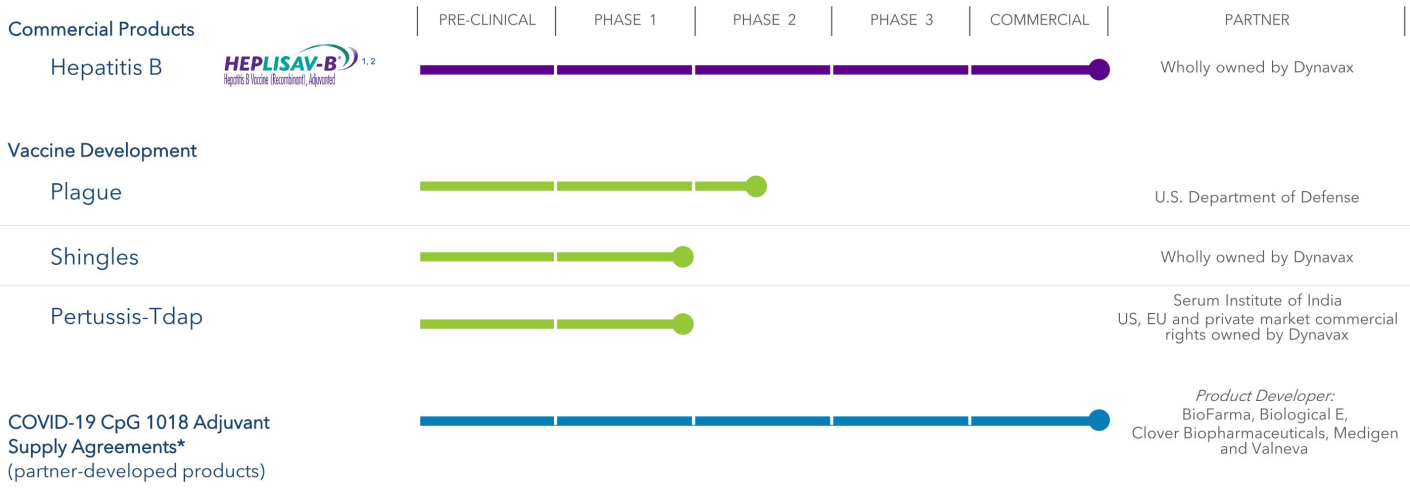
Our proprietary CpG 1018 adjuvant is being used to support worldwide vaccine development for infectious diseases which take an increasing toll on public health




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

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

# Diversified Pipeline Leveraging CpG 1018 Adjuvant




[1] Approved: U.S. commercial launch Q1-2018; EU commercial launch Q2-2022.
[2] Commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany.
*The information provided in this section was last updated January 6, 2023; please visit partner websites for more information.


# 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[1]

**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



1. Source: https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/facts-and-figures/

# 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]




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.



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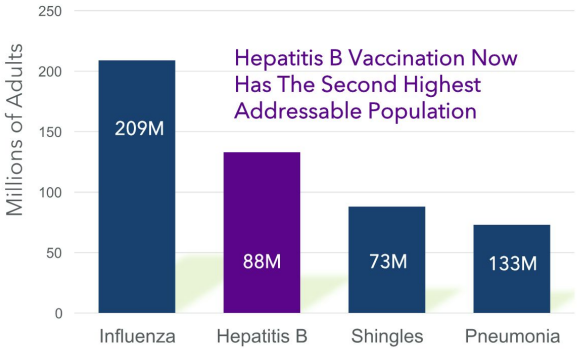
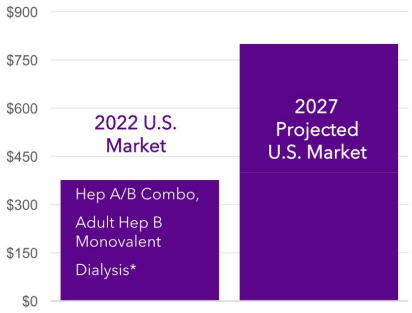
# Hepatitis B Market Opportunity

## Approximate Number of Adults Recommended for Vaccination in 2022




*Adults eligible for influenza vaccines calculated from population aged 18+ in 2022; adults eligible for shingles vaccines calculated using adults turning 50 years old in 2022, adults aged >50 who are unvaccinated based on CDC coverage rates, and immunocompromised adults aged 19-49; adults eligible for pneumonia vaccines included adults aged 65+ and at-risk adults aged 18-64 excluding smokers, patients with chronic heart disease, and patients who are immunocompromised; adults eligible for hepatitis B vaccination calculated using US census data published in 2018, CDC coverage data, and risk factor analyses.

## U.S. Adult Hepatitis B Vaccine Market Opportunity Projected to Double by 2027



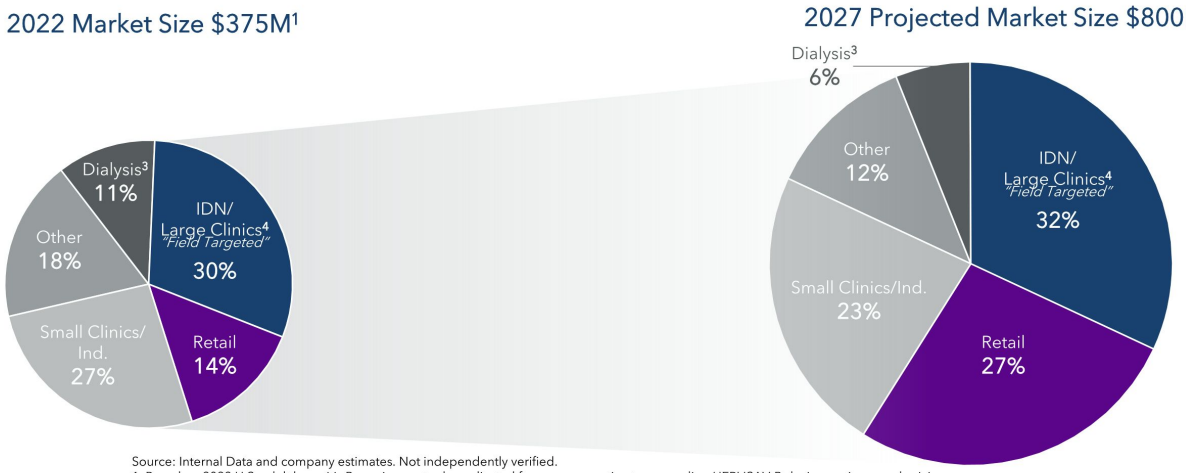

### Projected Hepatitis-B Market:

- ACIP universal recommendation has increased the number of eligible patients by ~100M people
- ACIP broadens and simplifies Hep B vaccine recommendations
- Dialysis-specific* dosing regimen data
- Improved compliance with two-dose advantage
- Targeted commercial investment driving growth in prioritized segments

Based on 2022 U.S. Hepatitis B vaccines market, adjusted for company estimates regarding HEPLISAV-B dosing regimen and pricing *The 4-dose regimen for the dialysis population is not currently approved regimen. Safety and effectiveness have not been established in patients on hemodialysis.

# Integrated Delivery Networks (IDN) and Retail are the Largest Growth Segments

HEPLISAV-B is the Market Leader in IDN/Large Clinics –
A Segment that will Drive Meaningful Growth from the ACIP Universal Recommendation




Source: Internal Data and company estimates. Not independently verified.
1 Based on 2022 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 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 currently approved regimen. Safety and effectiveness have not been established in patients on hemodialysis.
4 IDN and Large clinics are the segment targeted by our salesforce representing "Field-targeted"





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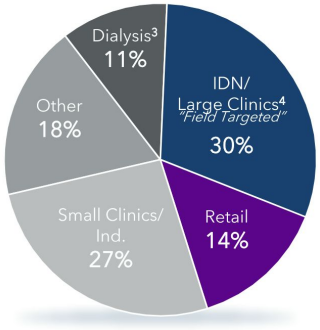
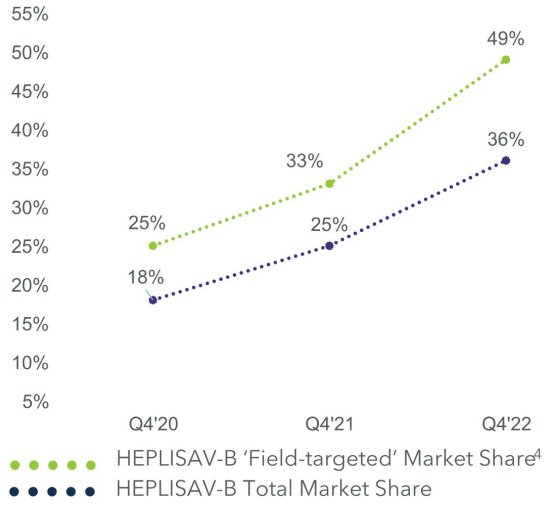
# Continued Growth in HEPLISAV-B Vaccine Market Share

## 2022 Adult Hepatitis B Vaccine Market Size $375M[1]




## HEPLISAV-B Vaccine Market Share[2]




Source: Internal Data and company estimates. Market Segments by dose distribution reflects Q4 2020, Q4 2021 and Q4 2022. Not independently verified.
1 Based on 2022 U.S. adult hepatitis B vaccines net sales, adjusted for company estimates regarding HEPLISAV-B dosing regimen and pricing.
2 Market share data are for Q4 of each year and do not reflect interim periods (including preliminary, estimated market share for Q4 2022).
3 The 4-dose regimen for the dialysis population is not currently approved regimen. Safety and effectiveness have not been established in patients on hemodialysis.
4 IDN and Large clinics are the segment targeted by our salesforce representing "Field-targeted".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# Vaccine Development

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

# High Unmet Need Exists for Addressing Resurgence of **Pertussis** Globally

Globally

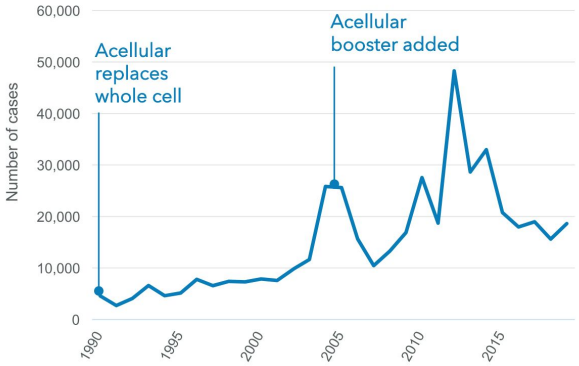
~24 million
cases of pertussis[2]

160,700
deaths[2]

In the U.S. Tetanus and diphtheria are rare, but pertussis continues to spread.[1]

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

Reported US Cases 1990-2019 [2]




**Waning efficacy:** Effectiveness decreases 40-60% four years post vaccination[2]

**Asymptomatic transmission:** current acellular vaccines do not prevent asymptomatic infection or transmission[3]

Sources: 1 Updated as of January 2023 (data through 2019) Source: Centers for Disease Control and Prevention (https://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html) 2 https://www.cdc.gov/vaccines/vd/dtap-tdap-td/public/index.html 3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4482312

# DV2-TDAP-01: Tdap Booster Vaccine Phase 1

## Competitive efficacy and safety profile emerging

CpG 1018 adjuvant expected to improve the durability and protection against pertussis colonization in the upper airways by redirecting T cell responses and enhancing protective antibody responses in a booster vaccine.

Randomized, blinded, active-controlled, dose escalation clinical trial to evaluate the safety, tolerability, and immunogenicity of an investigational Tdap booster vaccine utilizing CpG 1018 adjuvant compared to a licensed Tdap vaccine

**ANZCTR.ORG.AU IDENTIFIER:** ACTRN12620001177943p

Dose Ranging
Comparative
Multicenter (Australia)

Tdap-1018 1500 µg
Tdap-1018 3000 µg
Boostrix

138 Total Participants
90 Adults
48 Adolescents

16 Weeks
Study Duration

Safety & Tolerability
Immunogenicity

Trial initiated: Jan. 2021
Completed: August 2022

### Update and Next Steps:

**Phase 1 clinical results were presented in October 2022:**

- Adult and adolescent safety data demonstrated the Tdap vaccine candidate was well tolerated without safety concerns.
- Immunogenicity in adults and adolescents were consistent with expectations and support the plan to continue advancement of this clinical program.

**In 2023,** we intend to complete and evaluate NHP challenge study, assess regulatory pathway with FDA, to support initiation of our vaccine human challenge study

# Current Market-Leading **Shingles** Vaccine is Associated with Adverse Events[1] – New Vaccine Options Needed

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).

In the U.S. Herpes zoster rates are increasing among adults in the U.S., especially among younger adults. The reason for the increase is unknown. The rates among older adults are plateauing.[2]

In the U.S.

## 1 out of 3 people

will develop herpes zoster in their lifetime

**~1 million**
annual cases of herpes zoster

**1 case per 100**
annual incidence among people 60+ yrs.

**1 - 4%**
people with herpes zoster hospitalized for complications

1 Package Insert - SHINGRIX (fda.gov) 2. Clinical Overview of Herpes Zoster (Shingles) | CDC https://www.cdc.gov/shingles/surveillance.html
2 https://www.cdc.gov/shingles/hcp/clinical-overview.html

# DV2-ZOS-01: Shingles Vaccine Phase 1

## Opportunity to improve vaccine tolerability while maintaining comparable efficacy

We believe CpG 1018 adjuvant MOA is ideal for an improved shingles vaccine 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.

Randomized, active-controlled, dose-escalation, multi-center Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of investigational herpes zoster (shingles) vaccine utilizing glycoprotein E (gE) plus CpG 1018 adjuvant (Z-1018) with and without aluminum hydroxide (alum) compared to Shingrix®

CLINICALTRIALS.GOV NCT IDENTIFIER: NCT05245838

Dose Ranging
Comparative
Multicenter (Australia)

Z-1018
vs.
Shingrix

150 Total Participants
50-69 years of age

20 Weeks
Study Duration

Safety and Tolerability
Immunogenicity

Trial initiated: Jan. 2022
Completed: Oct. 2022

### Update and Next Steps:

### Topline data from Phase 1 clinical trial reported in Jan. 2023

- High antibody and CD4 positive T-cell vaccine response rates in all arms and similar to the comparator
- Robust increases in CD4 positive T-cells were observed in all Z-1018 arms, although lower than the comparator.
- Total frequency of solicited systemic adverse events and local post-injection reactions were similar across the Z-1018 arms and lower than the comparator

### Data to be submitted for presentation at an upcoming medical meeting in 1H:2023

# Plague Remains a Threat to Humankind

Plague is an infectious disease that can become severe if left untreated.

As seen with the 2022 Mpox (monkeypox) outbreak, rare diseases that are endemic in remote parts of the world can suddenly spread and become a global threat.

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.

## Yersinia Pestis

bacteria usually found in small mammals and their fleas that causes plague

## 7-10 days

flu-like symptoms develop in people infected with plague

## Bubonic

most common type of plague

## Pneumonic

deadliest and most rapid form of plague

## Vaccination

is an essential tool to prevent the spread of infectious disease, and timely accessibility is crucial to contain an outbreak. There is no approved vaccine in the U.S.



Source: WHO infographic: plague-february-2017-jpg.jpg (1500×2122) (who.int) What are Medical Countermeasures? | FDA

# DV2-PLG-01: Plague Vaccine Phase 2 Contract

Ongoing randomized, active-controlled, observer-blind, multicenter Phase 2 trial of the immunogenicity, safety and tolerability of rF1V vaccine with CpG 1018 adjuvant compared with rF1V vaccine alone in adults.

The trial is assessing a CpG-1018+alum two-dose regimen administered over one month compared to an alum-only adjuvanted three-dose regimen over six months.

**CLINICALTRIALS.GOV NCT IDENTIFIER:** NCT05506969

Multicenter (US)

CpG 1018+rFIV
rFIV

200 Healthy Adults

Safety and Tolerability
Immunogenicity

Trial initiated: Aug 2022
Ongoing through 2024

## Update and Next Steps:

**Phase 2 clinical trial** – Conducted in collaboration with, and funded by, the U.S. Department of Defense

MOA has potential to speed up time to protection with fewer doses compared to the 3-dose vaccine under development by U.S. Department of Defense.

# COVID-19 CpG 1018 Adjuvant Supply Business

# Continued Public Health Focus Despite Pandemic to Endemic Transition

Despite incredible progress, unmet needs remain in COVID-19 as the pandemic continues, with a significant portion of the world population remaining unvaccinated.

## Globally

**>657 million cases**[1]

Of COVID-19 have been confirmed

**>6.6M deaths**[2]

Have been attributed to COVID-19

## A Vaccine Gap

**13 billion doses**[3]

Of COVID-19 vaccines have been administered

**>28%**[4]

Of people worldwide remain **unvaccinated**

**The majority**[5]

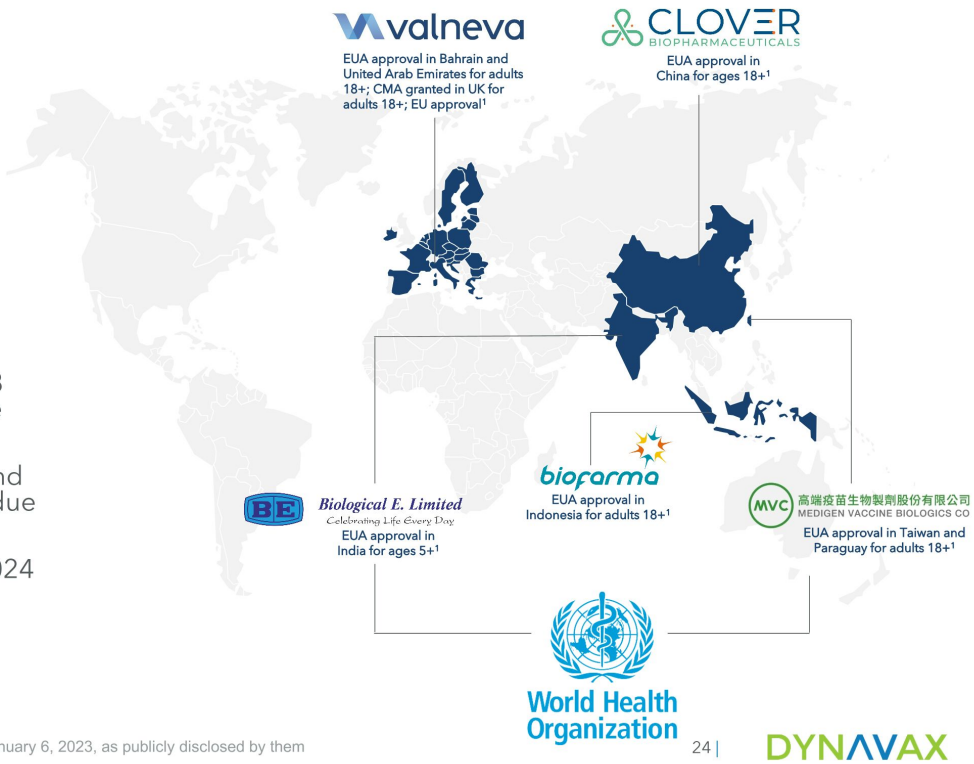
Of that 28% live in developing countries



Sources: 1, https://covid19.who.int confirmed cases are as of 6 January 2023, there have been approximately 658 million confirmed cases 2 https://covid19.who.int/ 3, 4, 5 https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html

# Well-positioned to Support Evolving Endemic COVID-19 Market

- Significant safety, efficacy and immunogenicity data for CpG 1018 adjuvant generated across multiple antigen platforms
- Minimal CpG 1018 adjuvant demand expected from customers in 2023 due to inventory on hand
- Additional potential demand for 2024 and beyond




 Product developer status as of January 6, 2023, as publicly disclosed by them

# Propelling Future Growth


# Delivering on Dynavax's Value Proposition

## Building on Key 2022 Accomplishments

- **HEPLISAV-B** preliminary net sales of $126 million (104% Y/Y growth)
- **Strengthened financial profile** through successful execution COVID-19 CpG 1018 adjuvant commercial supply
- **Tdap Phase 1 completed;** data presented in October 2022
- **Shingles Phase 1 completed;** topline results reported in Jan 2023
- **Plague Phase 2 trial initiated**

## 2023 Outlook

**HEPLISAV-B continued growth** and expansion of market share

**Advance differentiated clinical pipeline** including Shingles Phase 1 data to be presented in 1H 2023 and Tdap human challenge initiation by end of 2023

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