

**VBI**  
VACCINES

ACTIVATING THE POWER WITHIN

# Corporate Overview

# Forward-Looking & Safe Harbor Statements

Certain statements in this presentation that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively “forward-looking statements”).

The Company cautions that such statements involve risks and uncertainties that may materially affect the Company’s results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management.

Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to, the Company’s ability to regain and maintain compliance with the listing standards of the Nasdaq Capital Market, the Company’s ability to satisfy all of the conditions to the consummation of the transactions with Bii Biosciences, the Company’s ability to comply with its obligations under its loan agreement with K2 HealthVentures, the impact of general economic, industry or political conditions in the United States or internationally; the impact of the COVID-19 endemic on our clinical studies, manufacturing, business plan, and the global economy; the ability to successfully manufacture and commercialize PreHevbrio/PreHevbri; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of pipeline candidates and the commercialization of PreHevbrio/PreHevbri; the ability to obtain appropriate or necessary regulatory approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company’s ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company’s products.

A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company’s filings with the SEC and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the SEC on April 16, 2024, and filed with the Canadian security authorities at [sedar.com](https://www.sedar.com) on April 16, 2024, as may be supplemented or amended by the Company’s Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. All such forward-looking statements made herein are based on our current expectations and we undertake no duty or obligation to update or revise any forward-looking statements for any reason, except as required by law.



# About VBI Vaccines

VBI Vaccines is a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease

## Our product...

 **PreHevbrio**  
Hepatitis B Vaccine (Recombinant)

Approved by the FDA on  
November 30, 2021<sup>1</sup>

## Our pipeline...

... prioritizes **infectious  
disease and cancer  
indications**

Notable targets include:

- Hepatitis B (HBV)
- Glioblastoma (GBM)
- COVID-19, coronaviruses
- Cytomegalovirus (CMV)

## Our locations...

**Ottawa, Canada** ●  
Research Operations  
*R&D headquarters and facility*

**Cambridge, MA, USA** ●  
Corporate Headquarters  
*Central location in biotechnology hub*

**Rehovot, Israel\***  
Manufacturing Facility  
*GMP manufacturing facility  
for the production of  
PreHevbrio*



\*Expected to be purchased by Bii Biosciences mid-year 2024, upon completion of certain activities



<sup>1</sup>Subsequent marketing approvals received in 2022 for use in the EU/EEA/UK (PreHevbrio<sup>®</sup>), and Canada (PreHevbrio<sup>®</sup>). The vaccine is also approved for use in Israel as Sci-B-Vac<sup>®</sup>.

# Our Portfolio Targets Viruses with Both a Preventive and Therapeutic Application & Unmet Need



## HEPATITIS B VIRUS (HBV)

Globally, as many as

**350**MILLION

&

In the U.S., as many as

**2.2**MILLION

PEOPLE ARE CHRONICALLY INFECTED WITH HBV

... with nearly **1**MILLION ANNUAL DEATHS WW from HBV-related causes

The CDC estimates



**68%**

of U.S. people with chronic HBV are **UNAWARE** of their infection status



INCREASING THE LIKELIHOOD OF TRANSMISSION

Even though HBV is a vaccine-preventable disease...

**ONLY 30%**

OF ADULTS ARE FULLY VACCINATED AGAINST HBV IN THE U.S., leaving the majority at risk of HBV infection



## CYTOMEGALOVIRUS (CMV)

While most CMV infections are "silent", it infects

**1** IN EVERY **2** PEOPLE

... and may cause severe infections in newborns (congenital CMV) and in solid organ or bone marrow transplant recipients

CMV is also associated with several solid tumors, including **GLIOBLASTOMA (GBM)**, which is among the most common and aggressive malignant brain tumors

**12,000**

U.S. NEW CASES/YEAR

Median Overall Survival (OS)

**15** Mo.

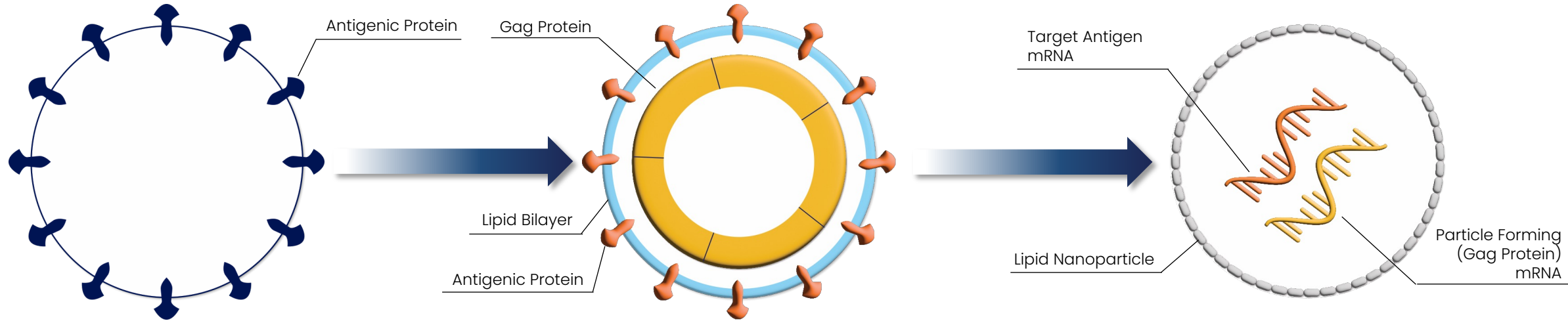
PRIMARY GBM<sup>1</sup>

**8** Mo.

RECURRENT GBM<sup>2</sup>

RECURRENT TUMORS DOUBLE IN SIZE **EVERY 6 WEEKS**

# Our Technology : Revolutionizing The Science of Virus-Like Particles (VLPs)



## VLPs

*Virus-Like Particles*

- Sub-unit vaccines with no infectious material
- VLPs mimic the natural presentation of viruses
- Few antigens self-assemble into orderly VLP structures: notably, this includes hepatitis B antigens

## eVLPs

*Enveloped Virus-Like Particles*

- eVLPs expand the list of potentially viable targets by providing a stable core (Gag protein) and a lipid bilayer
- Flexible and customizable – enabling potential for multiple antigen expression
- Highly immunogenic with demonstrated safety profile

## MLEs




























*mRNA-Launched eVLPs*

- Leverages the strengths of both eVLP and mRNA technologies – enabling efficient and customizable design
- Addition of genetic code for particle-forming structural protein (Gag) instructs cells to create eVLPs *in vivo*, driving potent, functional immune responses
- Fast manufacturing timelines – similar to other mRNA vaccine production platforms



VBI's portfolio consists of vaccines and immunotherapeutics derived from three variations of VLP technology platforms

# VBI's Portfolio : Focused on Both Sides of the Fight

| Disease   | Name/Program  | Tech. | Preclinical   | Phase 1  | Phase 2   | Phase 3   | Approved  |
|---|---|-------|---|--|---|---|---|
|  Hepatitis B                                       |   |       |   |  |   |   |   |
| Prevention  |  <sup>1,2,3,4</sup><br>Hepatitis B Vaccine (Recombinant) | VLP   |    |   |  |  |  |
| Treatment   | VBI-2601 (BR11-179)   | VLP   |    |   |  | <i>Licensed to Bii Biosciences<sup>5</sup></i>                                      |   |
|  Cytomegalovirus (CMV) & Virally Associated Tumors |   |       |   |  |   |   |   |
| Treatment (GBM)   | VBI-1901  | eVLP  |    |   |  |   |   |
| Prevention (CMV)  | VBI-1501  | eVLP  |    |   |   |   |   |
| Treatment   | Undisclosed   | MLE   |    |  |   |   |   |
|  Prevention of Other Viral Targets                 |   |       |   |  |   |   |   |
| COVID-19 & Coronaviruses  | VBI-2901 (multivalent)  | eVLP  |    |   |   |   |   |
| COVID-19 (Ancestral Strain)   | VBI-2902 (monovalent)   | eVLP  |    |   |   |   |   |
| COVID-19 (Beta Variant)   | VBI-2905 (monovalent)   | eVLP  |   |  |   |   |   |
| COVID-19 & Coronaviruses  | Undisclosed (multivalent)   | eVLP  |  |  |   |   |   |
| Prevention  | Undisclosed   | MLE   |  |  |   |   |   |
| Zika  | VBI-2501  | eVLP  |  |  |   |   |   |



<sup>1</sup>Approved for use in the U.S. for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older

<sup>2</sup>Approved for use in Israel, under the brand name Sci-B-Vac®, for active immunization against hepatitis B virus (HBV) infection

<sup>3</sup>Approved for use in the E.U., EEA, and U.K. under the brand name PreHevbri® [Hepatitis B vaccine (recombinant, adsorbed)] for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults

<sup>4</sup>Approved for use in Canada for active immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older

<sup>5</sup>WW license granted to Bii Biosciences in July 2023, and, subject to certain achievements, is expected to be sold to Bii Biosciences by mid-year 2024



# Recent Deal with Bii Biosciences Significantly Reduces VBI's Debt Liability

Announced February 14, 2024

- VBI to receive up to \$33M in consideration from Bii Biosciences, subject to achievement of certain activities, for:
  - \$10M : VBI's manufacturing capabilities and certain related assets at Rehovot manufacturing facility
  - \$18M : Intellectual property for VBI-2601 (immunotherapeutic HBV candidate), reduction in obligations from July 2023 agreements, and transfer of manufacturing technology for VBI-2601 to a CDMO of Bii's choice
  - \$5M : Exclusive Asia Pacific (APAC), minus Japan, license for VBI-1901 (GBM)
- Following completion of the full transaction, VBI expects its total debt principal with K2 HealthVentures to be significantly reduced from \$50M to \$17M
- Target completion date for the full transaction is June 30, 2024, however, certain components may close earlier
- In connection with the transaction, certain covenants in VBI's loan agreement with K2 have been amended as well



# VBI Team

## Management



**Jeff Baxter**  
President & CEO



**David E. Anderson, Ph.D.**  
Chief Scientific Officer



**Francisco Diaz-Mitoma, M.D., Ph.D.**  
Chief Medical Officer



**Nell Beattie**  
Chief Financial Officer &  
Head of Corporate  
Development



**John Dillman**  
Chief Commercial  
Officer

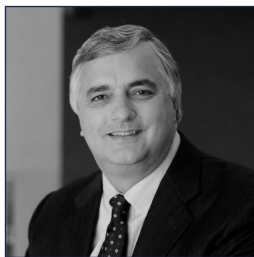


**Avi Mazaltov**  
Global Head of  
Manufacturing & SciVac  
General Manager

## Board of Directors



**Steve Gillis, Ph.D.**  
Chair



**Damian Braga**  
Director



**Joanne Cordeiro**  
Director



**Michel De Wilde, Ph.D.**  
Director



**Vaughn B. Himes, Ph.D.**  
Director



**Blaine H. McKee, Ph.D.**  
Director



**Jeff Baxter**  
Director



**Nell Beattie**  
Director





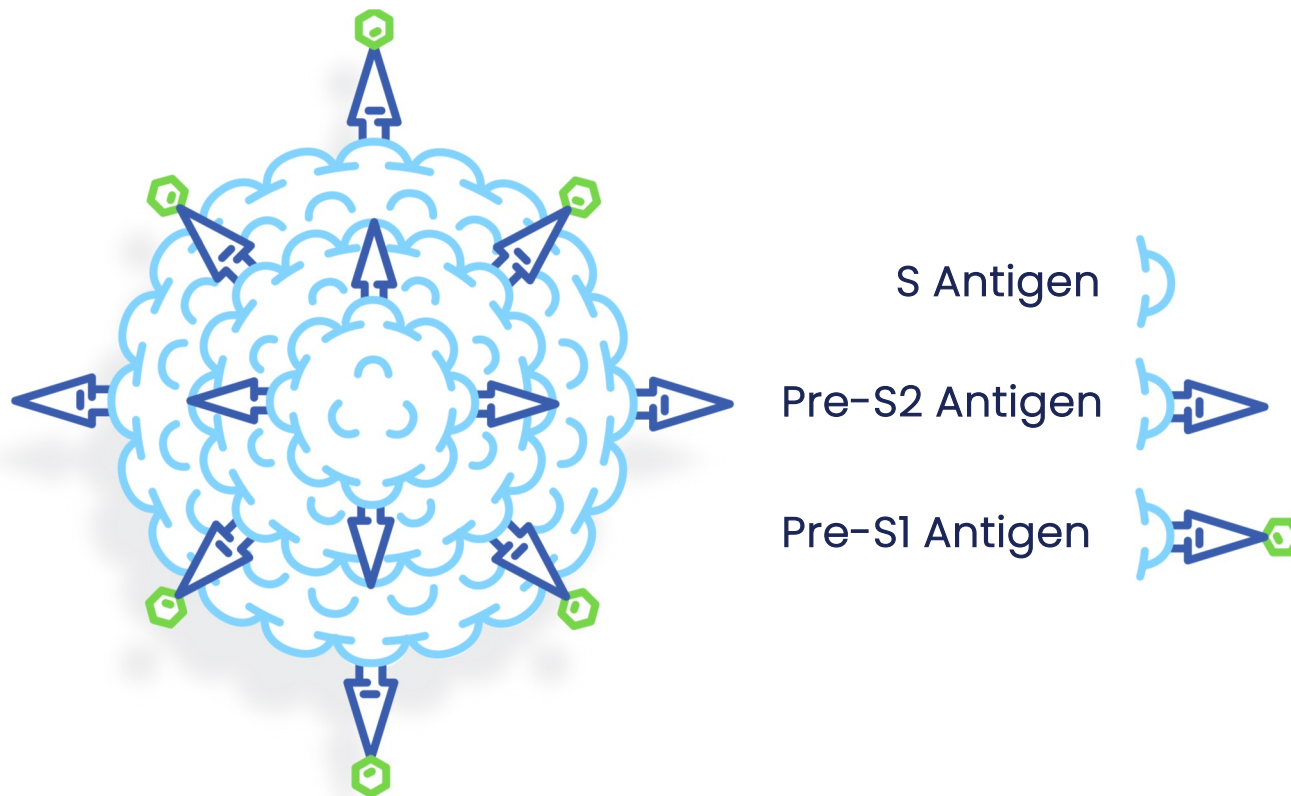


# PreHevbrio

Hepatitis B Vaccine (Recombinant)

# PreHevbrio is the Only 3-Antigen HBV Vaccine

PreHevbrio is scientifically differentiated from other HBV vaccines – expressing the three hepatitis B surface antigens (S, pre-S1, and pre-S2), and manufactured in mammalian cells (vs. yeast)



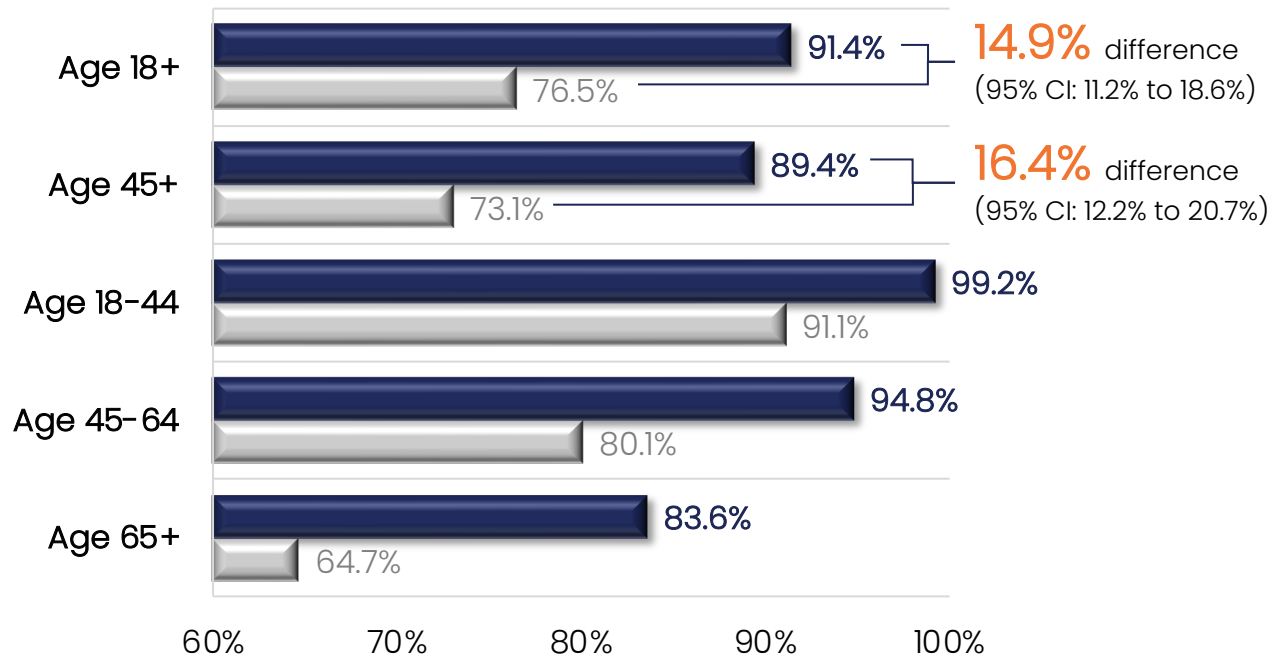
*The Pre-S1 and Pre-S2 proteins serve important roles in the viral invasion of hepatocytes, and in viral infection, viral assembly, viral replication, and stimulation of immune responses in the body*

# More Adults Achieved Seroprotection With PreHevbrio in Phase 3 Clinical Studies

## PROTECT Phase 3 Study

2-arm safety and immunogenicity study  
N=1,607 adults aged 18-90 years

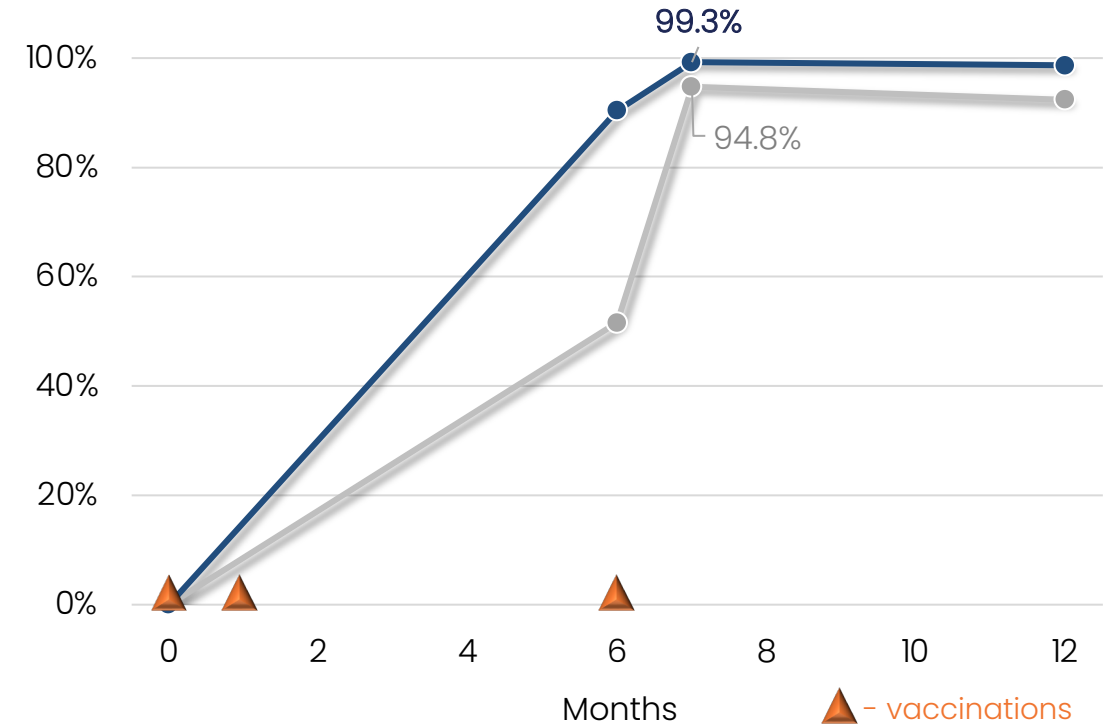
Seroprotection Rate (SPR)<sup>1</sup> at Day 196



## CONSTANT Phase 3 Study

4-arm lot-to-lot consistency study  
N=2,838 adults aged 18-45 years

Seroprotection Rate<sup>1</sup> (SPR) at Day 196



The integrated safety analysis demonstrated good tolerability with no unexpected reactogenicity. The most common adverse events in all age groups were injection site pain and tenderness, myalgia, and fatigue, all which generally resolved without intervention in 1-2 days

<sup>1</sup>Seroprotection rate defined as % of subjects who achieve anti-HBs titers  $\geq 10$  mIU/mL

Sources: PreHevbrio U.S. Full Prescribing Information; Vesikari T, et al. "Immunogenicity and safety of a 3-antigen hepatitis B vaccine vs a single-antigen hepatitis B vaccine: a phase 3 randomized clinical trial". *JAMA Network Open*. 2021; 4(10).

# Public Health Bodies are Changing Tactics – Renewed Prioritization in the Fight to Eliminate HBV

The logo for the Centers for Disease Control and Prevention (CDC), featuring the letters "CDC" in a large, white, sans-serif font against a blue background with white diagonal lines.

CENTERS FOR DISEASE  
CONTROL AND PREVENTION

- In April 2022, the CDC changed its adult HBV vaccination recommendation from risk-based for all adults to a **universal recommendation for adults aged 19–59 years**
- Recommendation change expected to greatly increase the number of adults vaccinated each year – ~70% of all adults in the U.S. are unvaccinated today



- Both **Healthy People 2020** & the **Viral Hepatitis Strategic Plan 2021–2025** include notable targets to:
  - Reduce the rate of acute HBV infection
  - Increase infection awareness
  - Reduce the rate of HBV–related deaths



- For the first time ever, the **WHO called for elimination of viral hepatitis B by 2030**, included in GHSS on viral hepatitis 2016–2021



# Commercialization Partnerships

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## United States Partner

- Includes VBI-dedicated leadership, medical, market access, and sales teams
- Syneos Health selected as partner for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers



## European Partner

- Partnership for the marketing, sales, and in-country distribution of PreHevbri® in initial European markets, including: the U.K., Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands
- Valneva selected as a partner for their extensive vaccine commercialization experience, local knowledge, and relationships



## APAC Partner

- Partnership for the development and commercialization of PreHevbri® in Asia Pacific countries, excluding Japan



# U.S. Market & 2023 Commercial Update

## U.S. Adult HBV Vaccine Market

2019 (Pre-COVID):

4.8M doses

Growing ~6% year over year

During COVID:

~53% decrease in total annual market



2022: 4.1M doses

2023: 5.0M doses



5% increase from Pre-COVID levels

The 2022 CDC Universal Recommendation is anticipated to increase the overall addressable market:

70% of all adults in the U.S. are unvaccinated today



Sources: Internal data and company estimates

## 2023 Commercial Update

2023 Net Sales:

\$3.1M



234% increase from 2022

PreHevbrio is now available to purchase at:



- CDC adult vaccine contract
- Three of the top 10 regional retail pharmacy networks
- U.S. Department of Veterans Affairs (VA)
- Federal Bureau of Prisons
- Certain military treatment facilities (MTFs)

Work is underway to expand the number of retail partners, U.S. integrated delivery networks (IDNs) and hospital systems that offer PreHevbrio

Preliminary 2024 U.S. Sales:

- Through early March 2024, U.S. sales volume totaled approximately 65% of 2023 full year volume, demonstrating substantial outpacing of 2023 on a volume basis





# **Glioblastoma (GBM)**

CMV-Associated Tumors

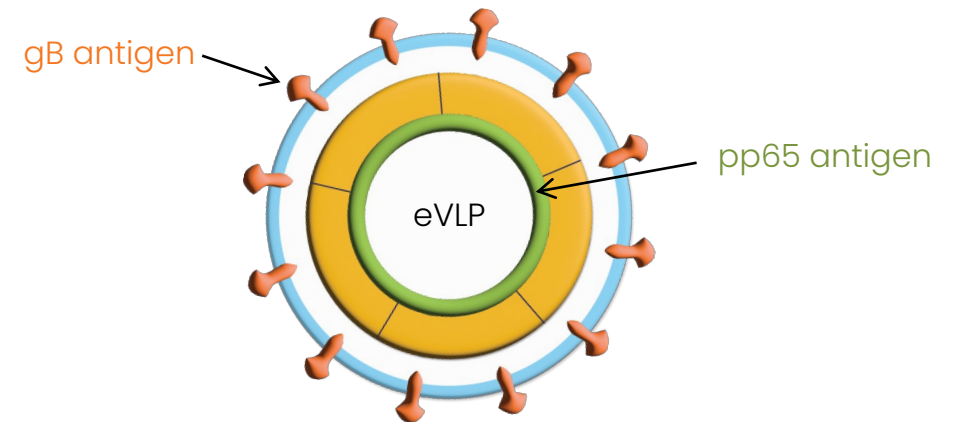
# Unique Approach to Immuno-Oncology

## CMV as a Foreign Viral Antigen

- 90% of some solid tumors, including glioblastoma (GBM)<sup>1</sup>, breast cancers<sup>2</sup>, and medulloblastomas<sup>3</sup> are CMV+ tumors
- CMV is not causative, but can influence disease progression of CMV+ tumors
- Because CMV is so broadly (and differentially) expressed on tumor cells, but not on healthy cells, a potent CMV vaccine has the potential to make “cold tumors, hot”
- GBM is among the most common and aggressive malignant brain tumors with few treatment options available

## VBI's Enveloped Virus-Like Particle (eVLP) Approach

*VBI-1901: Bivalent eVLP expressing two of the most immunogenic CMV antigens*

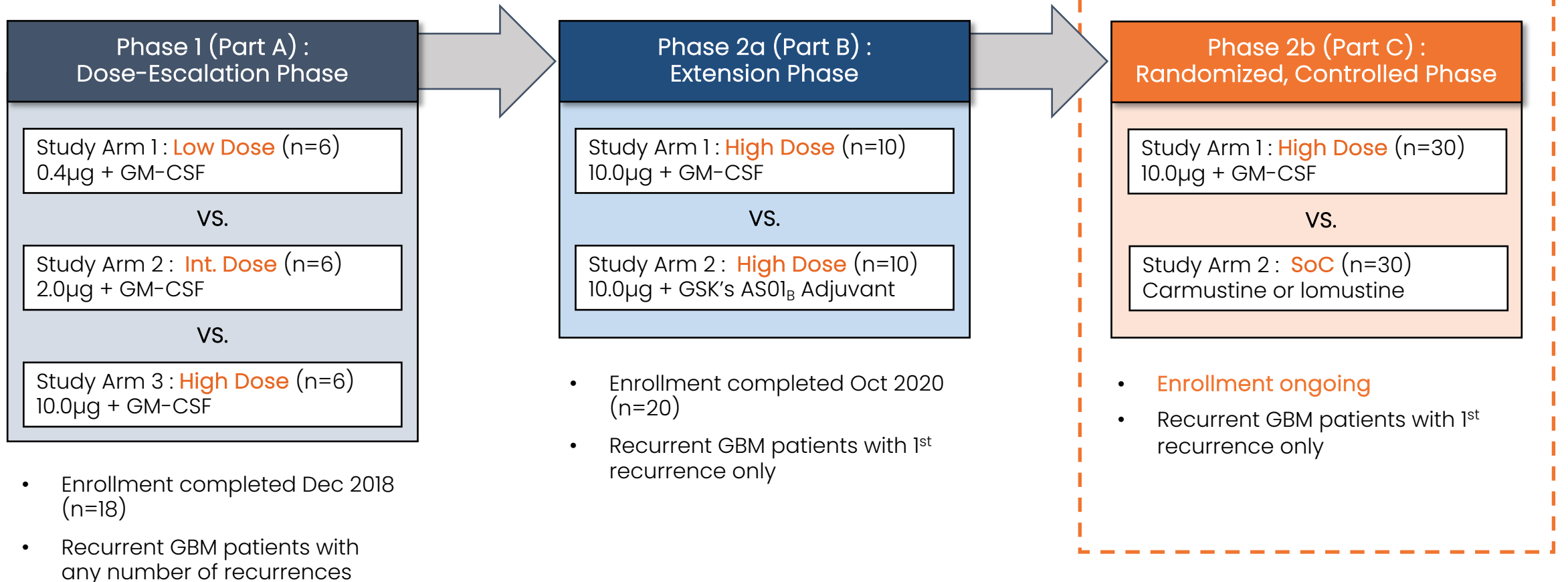


### Key Features:

- Internal antigen expression elicits T cell immunity
- Stimulated innate immunity



# Phase 1/2 Recurrent GBM Study Design & Objectives



# Data from Part A & B of Ongoing Phase 1/2 Study

As at August 1, 2023

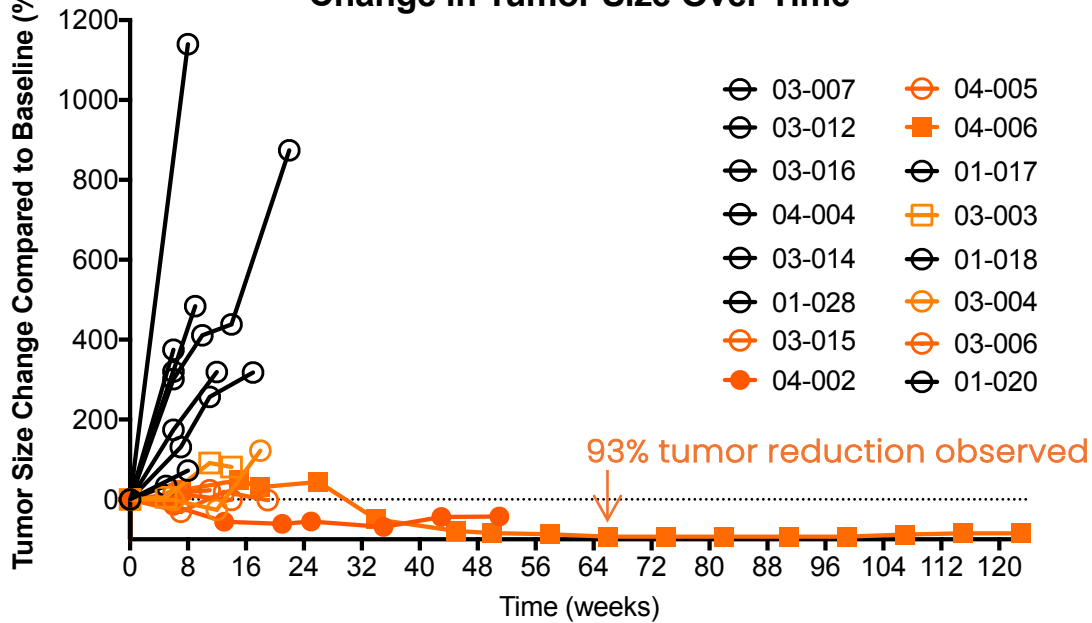
Based on the below results, U.S. FDA granted Fast Track Designation and Orphan Drug Designation to VBI-1901 + GM-CSF for the treatment of recurrent GBM patients with first tumor recurrence

## Tumor Responses

High Dose: Parts A & B

Disease Control Rate : 44% (n=7/16)  
2 Partial Responses (PR) + 5 Stable Disease (SD)

### Change in Tumor Size Over Time



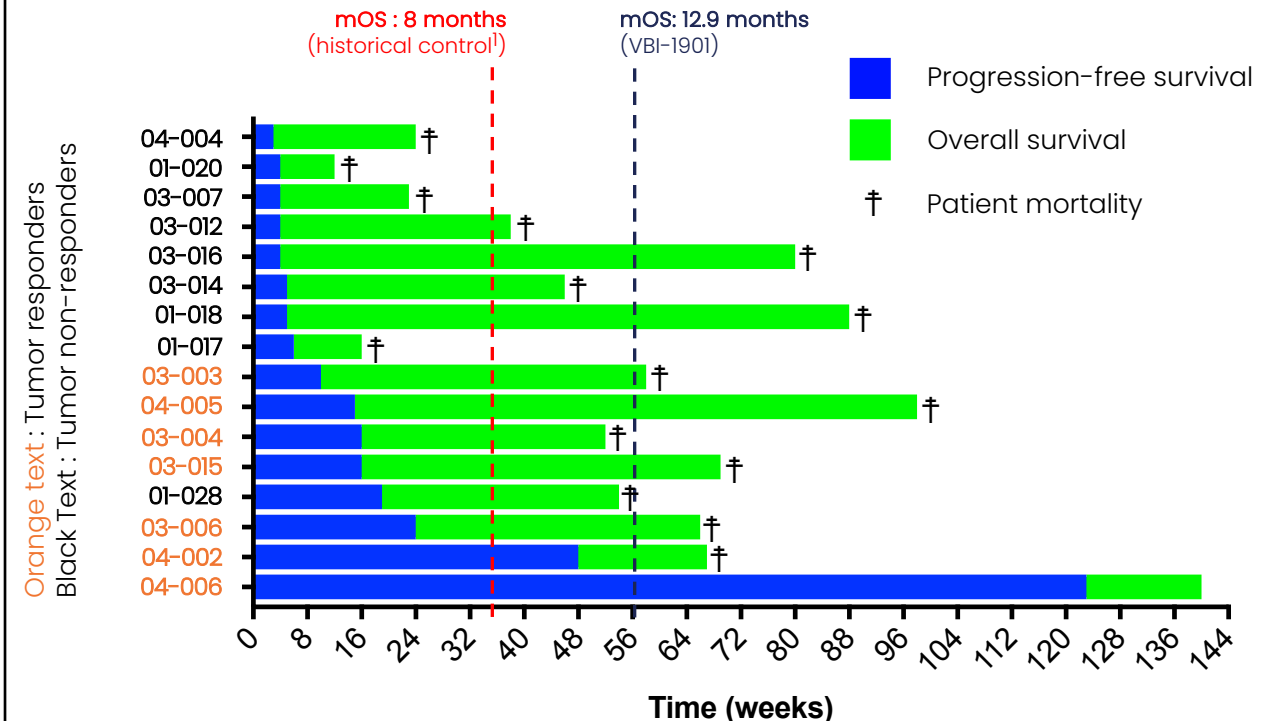
#### Legend:

- Progressive Disease
- Stable Disease (SD)
- SD + Pseudo-progression
- Partial Response (PR)
- PR + Pseudo-progression

## Clinical (Survival) Responses

High Dose: Part B

mOS reached at 12.9 months vs. 8 months with historical control  
12-month OS : 62.5% (n=10/16)

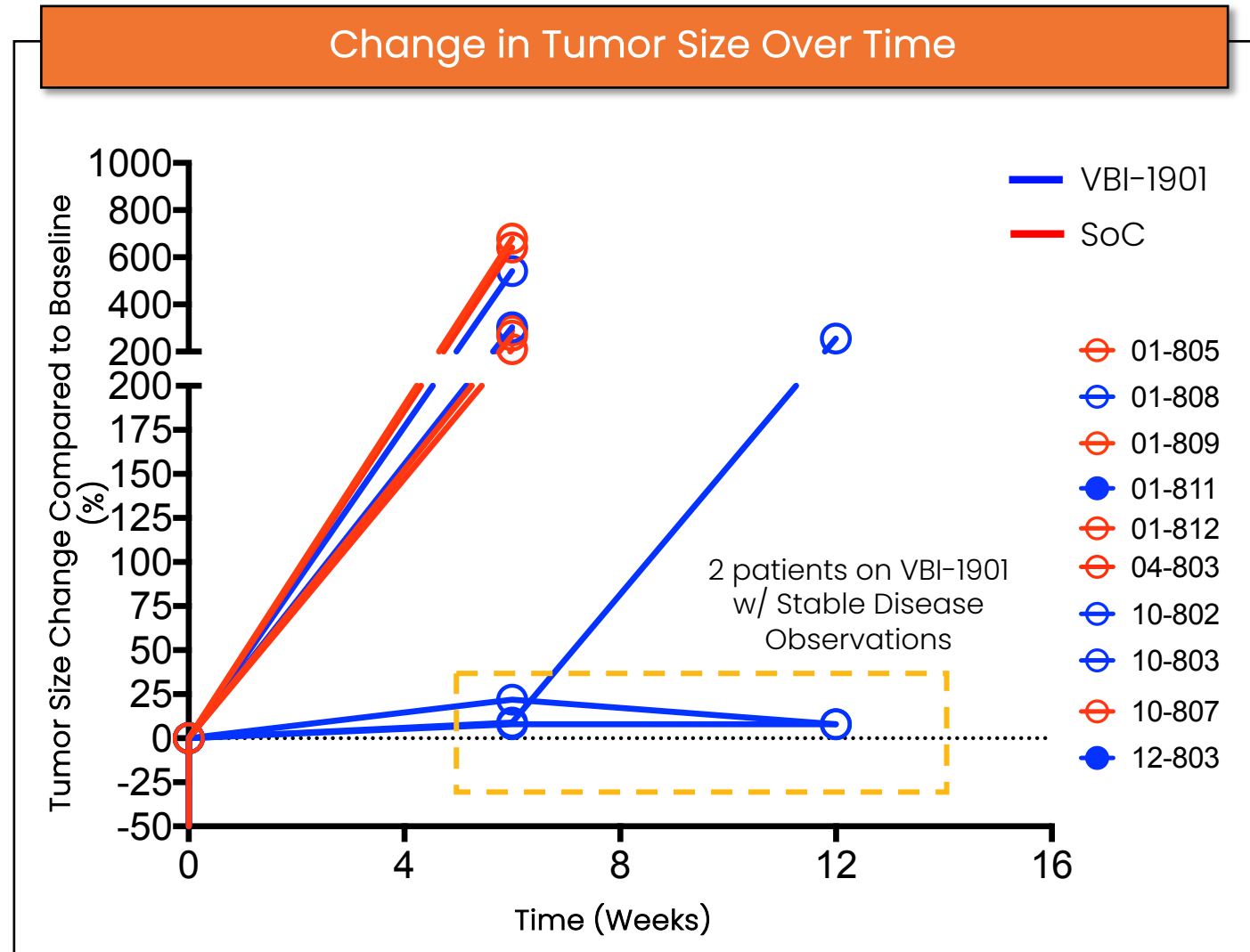


Source: 2024 World Vaccine Congress Washington (VBI presentation); <sup>†</sup>Taal W, Oosterkamp HM, Walenkamp AME, et al. Lancet Oncol. 2014; \*Tumor responses in glioblastoma patients are classified according to the Response Assessment in Neuro-Oncology (RANO) criteria, which defines a partial response (PR) as a greater than 50% reduction in the sum of products of perpendicular diameters of all measurable enhancing lesions compared with the baseline, sustained for at least four weeks, with no new lesions or clinical progression of disease

# Early Tumor Response Data from Part C (Phase 2b) of Ongoing Phase 1/2 Study

- 17 patients have been randomized and received first dose of treatment as of March 22, 2024
  - N=8 : Standard-of-Care (SoC) arm (Carmustine or lomustine)
  - N=9 : VBI-1901 arm
- 11 patients currently evaluable for tumor response assessment
  - 0/6 patients on SoC have been on protocol for longer than 6 weeks
  - 2/5 patients on VBI-1901 have stable disease (12 weeks without tumor progression)

Separation of tumor response trends observed to date in SoC arm and VBI-1901 arm is expected based on data from Part A and B and known efficacy of SoC



# Summary and Next Steps for VBI-1901

## Summary of Part A&B

- ~5-month improvement in mOS observed vs. historical standard-of-care (12.9 months vs. 8 months)
- 12-month OS : 62.5% (n=10/16)
- 2 partial tumor responses (PRs)
- 93% tumor reduction seen in one patient who remained on treatment > 28 months
- 44% disease control rate achieved (n=7/16)
- Study results foundational for Part C randomized, controlled trial under FDA Fast-Track Designation

## Early Data from Part C

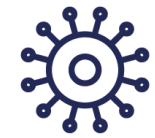
- Early data are consistent with data from Part A and Part B
- To date, 40% disease control rate in VBI-1901 study arm vs. 0% in standard-of-care study arm
- Already observing separation in tumor response trends between the two study arms
- Pending tumor response rates and overall survival data, results may provide potential for Accelerated Approval under FDA Fast Track Designation

## Next Steps

- 14 clinical sites are actively recruiting across the United States
  - Two new sites came online in March 2024, with another site expected in April
  - Enrollment in Q1 2024 has been 2x the enrollment rate observed in Q4 2023
- Additional interim data expected mid-year and year-end 2024



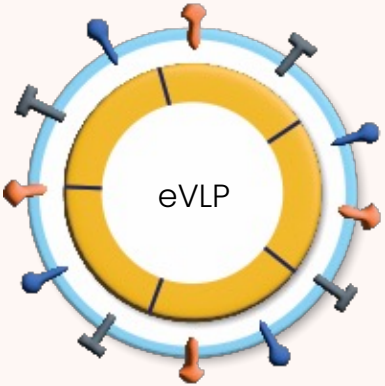
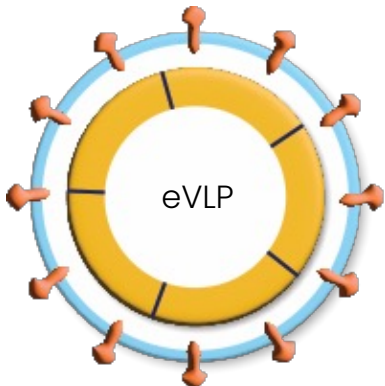
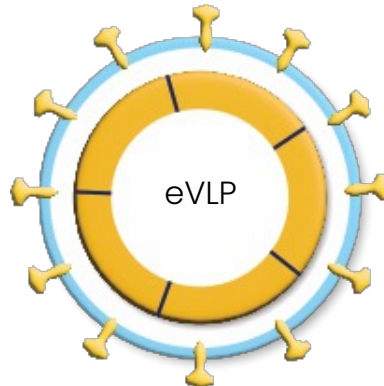




# Coronaviruses

# VBI is Committed to the Long-Term Protection Against Coronaviruses

VBI's coronavirus pipeline program (VBI-2900) is designed with the goal of eliciting broad and durable immune responses against COVID-19 and coronaviruses

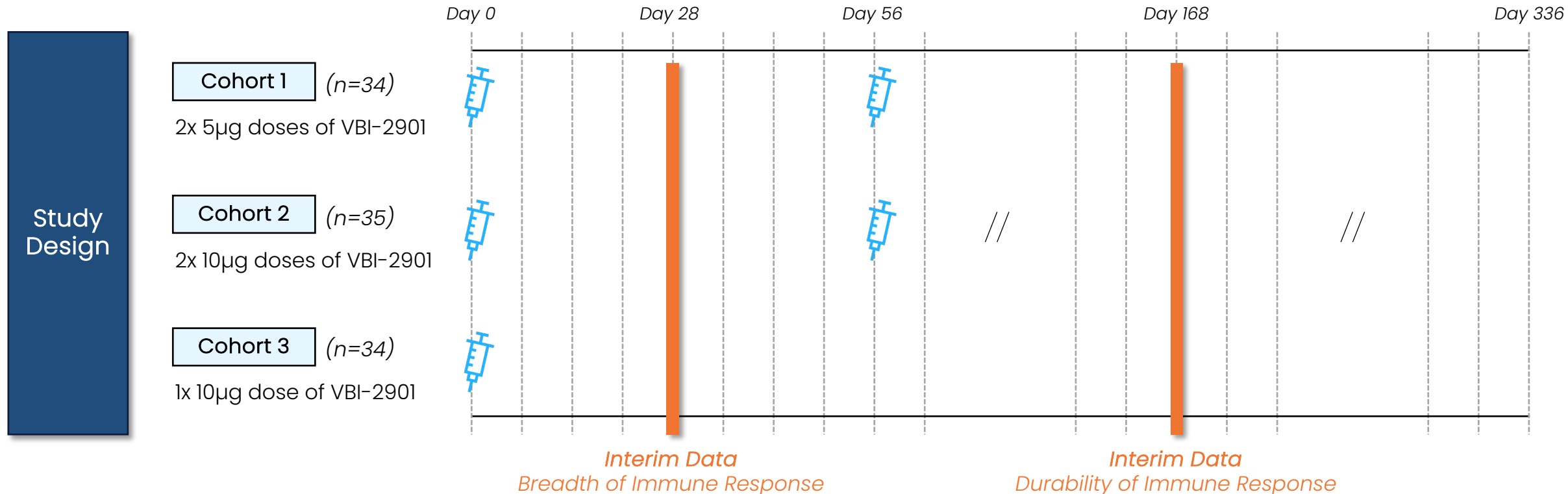
|                  | VBI-2901<br><i>Multivalent Pan-Coronavirus</i>                                     | VBI-2902<br><i>Monovalent COVID-19</i>   | VBI-2905<br><i>Monovalent COVID-19<br/>B.1.351 Variant</i>                           | Undisclosed<br><i>Multivalent Candidates</i>  |
|------------------|--|--|--|---|
| Schematic        |  |  |  | <i>A suite of additional multivalent coronavirus vaccine candidates designed to evaluate the potential breadth of VBI's eVLP technology</i> |
| Construct Design | Ancestral COVID-19, MERS, SARS spike antigens                                      | Ancestral COVID-19 spike antigen   | COVID-19 B.1.351 (501Y.V2) spike antigen   | Undisclosed   |

✓ Phase 1 Complete:  
eVLP Platform PoC Achieved



# VBI-2901 Phase 1 Study Design

Randomized, open-label Phase 1 study of VBI-2901 in n=103 healthy adults aged 18-64 previously vaccinated with 2+ doses of COVID-19 vaccines licensed by Health Canada



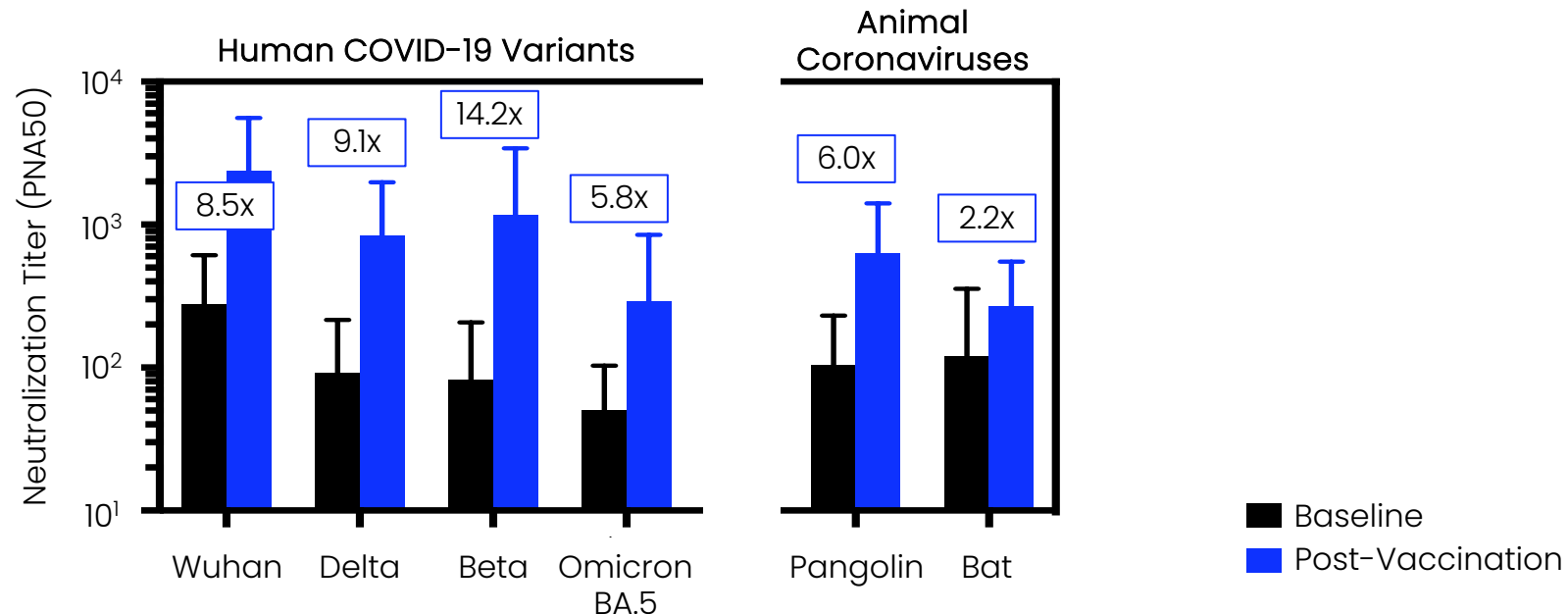
- First clinical data from a pan-coronavirus vaccine candidate – interim data announced September 2023
- No safety signals or Grade 3/4 adverse events observed – consistent with known safety profile of eVLP platform technology
- Peak immune responses were achieved in adults who received a single 10µg dose of VBI-2901



# Interim Phase 1 Data : Breadth of Immune Response

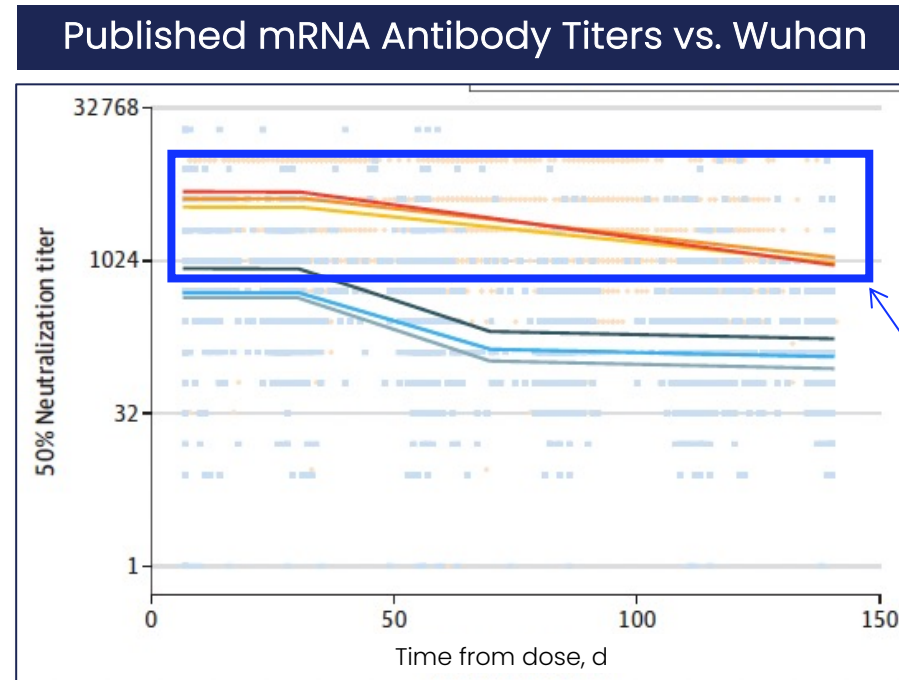
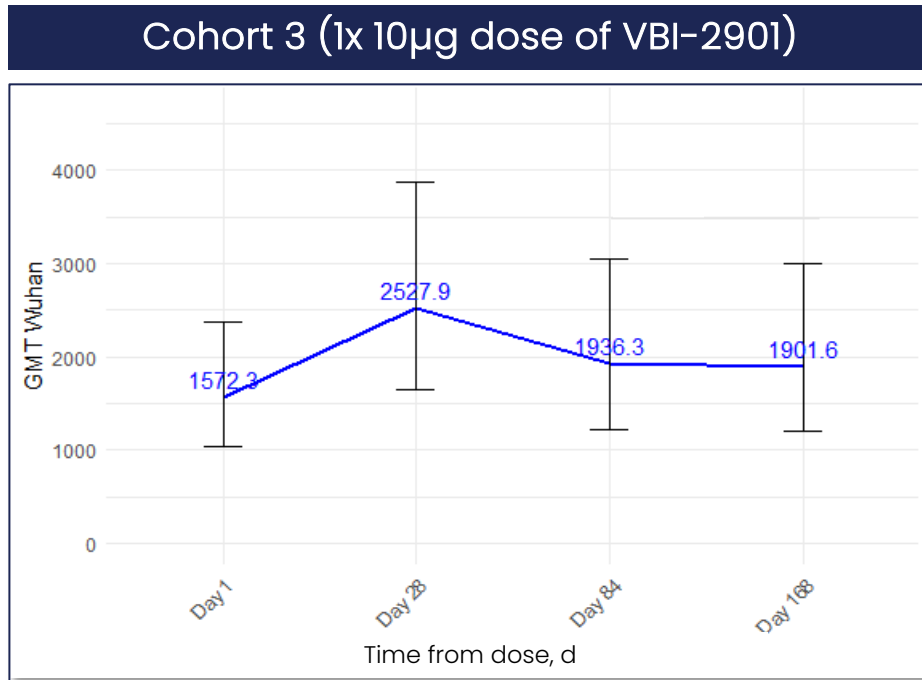
VBI-2901 elicited high neutralizing responses against a panel of COVID-19 variants, including Wuhan, Delta, Beta, Omicron BA.5, and multiple animal coronaviruses

- All participants saw boosting and/or high neutralizing responses against a panel of COVID-19 variants (as assessed at Day 28 – 4 weeks after the first dose of VBI-2901)
- Despite the enrollment criteria, many participants had high baseline titers of neutralizing antibodies, however, ~10% of participants who received 1+ dose of 10µg of VBI-2901 had low baseline titers (GMT: 148 IU<sub>50</sub>/mL vs. GMT: 1998 IU<sub>50</sub>/mL for all other participants) – this population is considered most at-risk of infection
- In this high-risk group, significant vaccine-induced boosting of neutralizing antibodies was observed at Day 28 with one dose of VBI-2901 10µg:



# Interim Phase 1 Data : Durability of Immune Response

Durability of protective titers induced by VBI-2901 were maintained through interim data point at Day 168 (6 months) – substantially more persistent compared to published durability data for a licensed mRNA vaccine



vs.

- Only ~25% reduction in GMT against Wuhan after 5 months vs. peak immune responses
- Similar enhanced durability trends observed against all tested variants

- ~77% reduction in GMT against Wuhan after only 4 months vs. peak immune responses
- More aggressive decline in durability seen against other variants tested in study, including Omicron, with 4x–10x lower titers 4 months after 3<sup>rd</sup> vaccination



# Partnerships & Milestones

## Partnerships

VBI's coronavirus program is supported by partnerships with:

**Canada**

Awarded up to \$56M CAD contribution

**CEPI**

Awarded up to \$33M USD of funding

**NRC - CMRC**

Development collaboration

**RESILIENCE**

Development and manufacturing partnership



## Recent & Upcoming Milestones

- ✓ **2021/2022** : Data from Phase 1 studies demonstrated eVLP candidates are highly potent at low clinical doses, with generally favorable safety and tolerability profiles
- ✓ **Sept 2022** : Initiation of Phase 1 study of multivalent pan-coronavirus vaccine candidate (VBI-2901)
- ✓ **Sept 2023** : Interim Phase 1 data announced demonstrating VBI-2901 was well-tolerated and induced broad and durable protective titers against variants of concern
- **2024** : Additional data expected from Phase 1 study



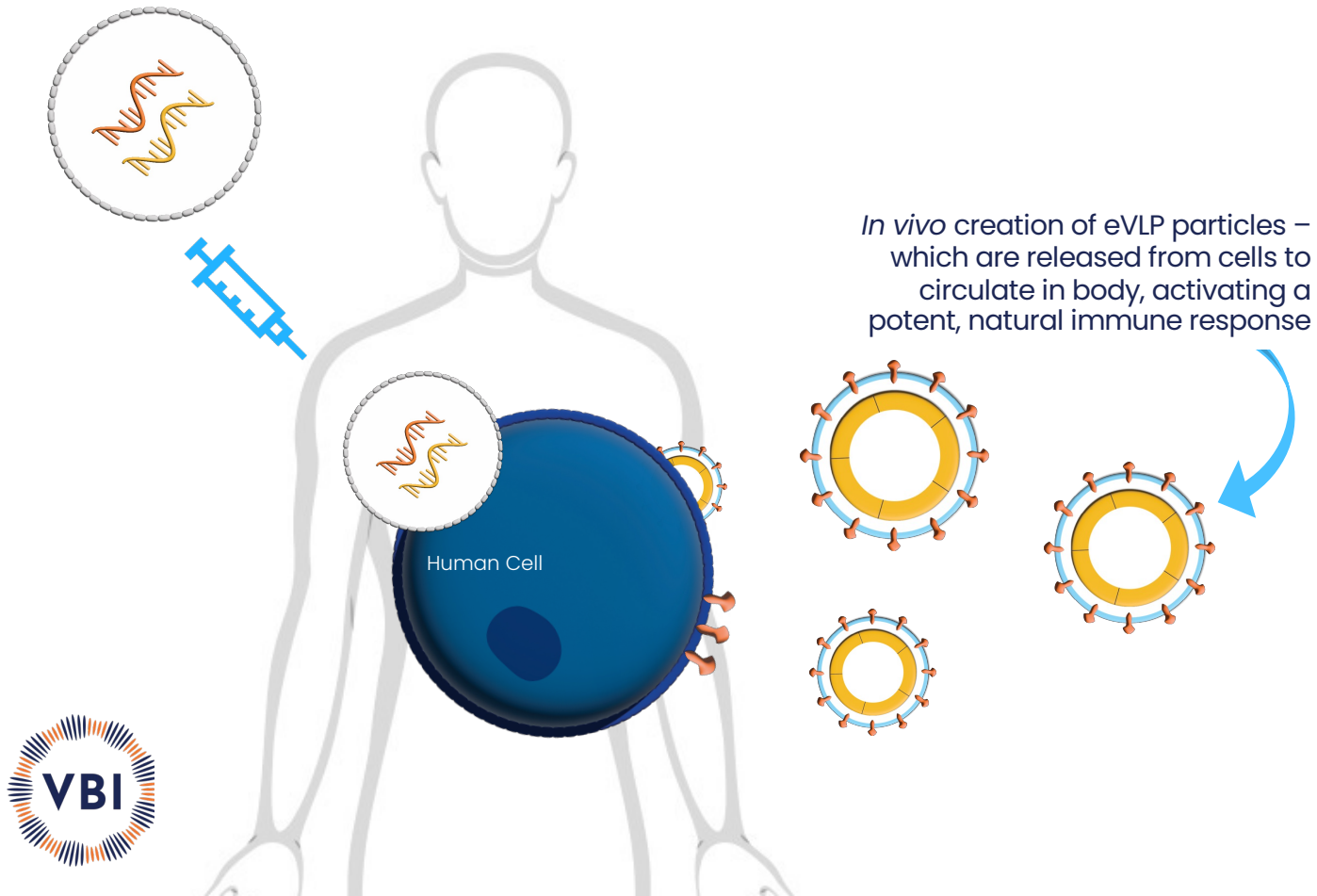


# MLE Platform

mRNA-Launched eVLP Technology

# mRNA-Launched eVLPs (MLE) : Novel Approach to Particulate Vaccines

VBI's MLE vaccine candidates deliver genetic code for target antigens, in addition to code for a structural viral protein (Gag Protein) to the immune system. The addition of this protein – the same protein at the core of VBI's eVLPs – teaches cells to create eVLPs *in vivo*, which circulate in the body and provoke potent B-cell and T-cell immune responses



## Additional MLE platform benefits:



### Potent Functional Immunity

- Elicits enhanced functional neutralizing antibodies
- Induces generation of polyfunctional CD4 and CD8 T-cell responses



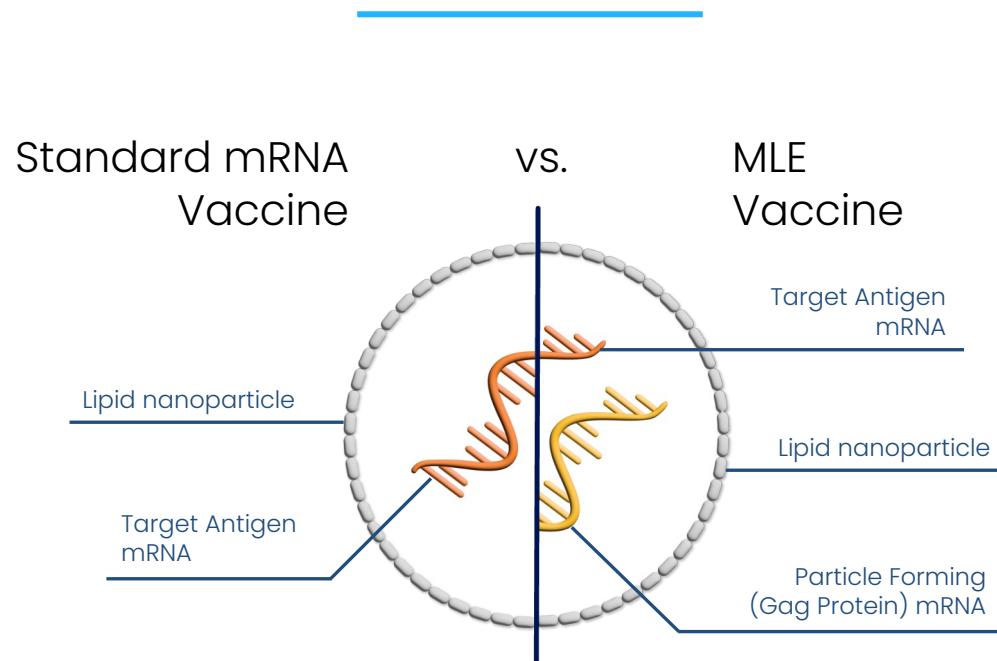
### Efficient & Customizable

- Fast manufacturing timelines – similar to other known mRNA vaccine production platforms
- Building upon flexibility of eVLP platform, target antigens can be expressed both internally and externally

# Recent & Upcoming Milestones

## Potential for business development partnerships

VBI's MLE technology continues to be evaluated by potential partners



## Recent & Upcoming Milestones

- ✓ **Oct 2023** : Announced expansion of proprietary technology platforms with development of novel mRNA-launched eVLP ("MLE") program
- ✓ **Apr 2024** : Announced expanded partnership with Canadian Government, supported by CAD\$28M funding award, to advance MLE platform
- **2024** : MLE technology under evaluation by potential partners



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