



# CORPORATE OVERVIEW

MAY 2021

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Frank Bedu-Addo Ph.D. President & CEO



**PDS Biotechnology**

Nasdaq: PDSB

*Developing powerful, safe, versatile  
immunotherapies*



## Forward-Looking Statements

This presentation contains forward-looking statements about PDS Biotechnology Corporation (“PDSB”), and its businesses, business prospects, strategies and plans, including but not limited to statements regarding anticipated pre-clinical and clinical drug development activities and timelines and market opportunities. All statements other than statements of historical facts included in this presentation are forward-looking statements. The words “anticipates,” “may,” “can,” “plans,” “believes,” “estimates,” “expects,” “projects,” “intends,” “likely,” “will,” “should,” “to be,” and any similar expressions or other words of similar meaning are intended to identify those assertions as forward-looking statements. These forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those anticipated.

Factors that may cause actual results to differ materially from such forward-looking statements include those identified under the caption “Risk Factors” in the documents filed with the Securities and Exchange Commission from time to time, including its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Except to the extent required by applicable law or regulation, PDSB undertakes no obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

The most significant barrier to effective immunotherapy has been their inability to promote adequate CD8+ killer T-cell responses *in vivo* resulting in diminished efficacy

PDS Biotech's Versamune<sup>®</sup>-based immunotherapies promote a powerful *in vivo* tumor-specific CD8+ killer T-cell response

Versamune<sup>®</sup>-based therapies also:



Generate a strong CD8+ T-cell memory response resulting in long-lasting efficacy



Generate potency without systemic side effects



Are versatile and shown to be effective on their own or in combination with other drugs to improve their efficacy

# PDS Biotech is a clinical stage biotechnology company developing a pipeline of immunotherapies based on the proprietary Versamune<sup>®</sup> platform

## CORPORATE OVERVIEW

- Biopharma developing novel cancer treatment candidates and T-cell-activating vaccine candidates for infectious diseases
- **Three** phase 2 oncology clinical trials in progress to initial data releases in 2021
- Clinical partnerships with Merck, MD Anderson and National Cancer Institute
- ~15 employees with headquarters in Florham Park, NJ
- Debt free with approximately **\$29.5M in cash** as of 3/31/21\*

## VERSAMUNE<sup>®</sup> PLATFORM

- NCI-initiated phase 2 trial in advanced HPV-cancer reported preliminary efficacy in 83% (5 of 6) of HPV16-positive patients who failed both chemotherapy and/or radiation treatment
- Pre-clinical studies demonstrated potential to work with a wide array of oncogenes and viral antigens
- Multiple composition and application patents valid through mid-2030s

# PDS Biotech's robust Versamune<sup>®</sup>-based pipeline is being developed in partnership with the leaders in immuno-oncology and infectious disease

PRODUCT	INDICATION	COMBINATION	PC	P1	P2	P3	R	PARTNER(S)
<b>Oncology</b>								
<u>PDS0101 (HPV16)</u>	First line treatment of recurrent / metastatic head and neck cancer	KEYTRUDA <sup>®</sup>	PDS Biotech Funded					MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	Bintrafusp alfa Mg241	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0101 (HPV16)</u>	Stage IIb-IVa Cervical cancer	Chemo-radiation	Partner Co-Funded					THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
<u>PDS0102 (TARP)</u>	Acute Myeloid Leukemia, Prostate and Breast Cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC-1)</u>	Breast, Colorectal, Ovarian and NSCLC Cancer	TBD	Partner Co-Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	TBD	PDS Biotech Funded					
<b>Infectious Disease</b>								
<u>PDS0203 (SARS-CoV-2)</u>	Prevention of COVID-19		Partner Co-Funded					Farma core MCTI BLANVER
<u>PDS0201 (M-tuberculosis)</u>	Prevention of tuberculosis		Partner Co-Funded					Farma core
<u>PDS0202 (influenza)</u>	Universal prevention of influenza		Partner Co-Funded					NIH National Institute of Allergy and Infectious Diseases

PDS Biotech Funded 

Partner Co-Funded 

\*Consortium of PDS Biotech, Farmacore and Blanver. Funding provided by The Ministry of Science, Technology and Innovation of Brazil (MCTI)

# PDS Biotech executive team has demonstrated success in the development and commercialization of leading pharmaceutical products

## Frank Bedu-Addo, PhD Chief Executive Officer

- Senior executive experience with management of strategy and execution at both large pharma and biotechs
- Notable drug development:  
Abelcet<sup>®</sup> (Liposome Company/ Elan)  
PEG-Intron<sup>®</sup> (Schering-Plough/ Merck)



## Seth Van Voorhees, PhD Chief Financial Officer

- Senior executive experience with over 20 years of experience in high tech companies
- In-depth experience with M&A transactions, capital markets, business development and investor relations



## Lauren V. Wood, MD Chief Medical Officer

- >30 years of translational clinical research experience
- Former Director of Clinical Research at National Cancer Institute Center for Cancer Research (Cancer Vaccine Branch)



## Gregory Conn, PhD Chief Scientific Officer

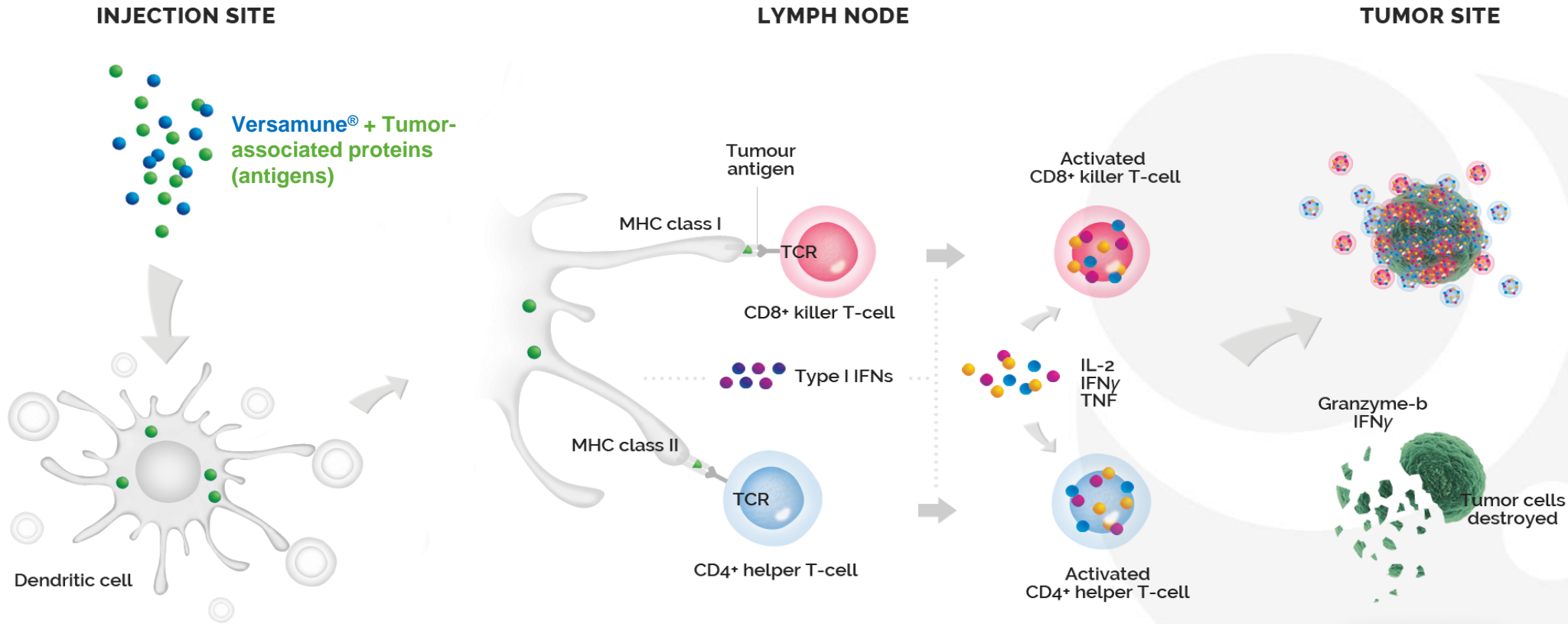
- Co-founder
- >35 years of drug development experience
- In-depth experience with biotech drug discovery, product development and manufacturing





# Introduction to the Versamune<sup>®</sup> Platform

# Versamune<sup>®</sup> is designed to induce a robust and targeted anti-tumor response *in vivo* when administered with a tumor-associated antigen



Promotes uptake of vaccine or immunotherapy and entry into lymph nodes

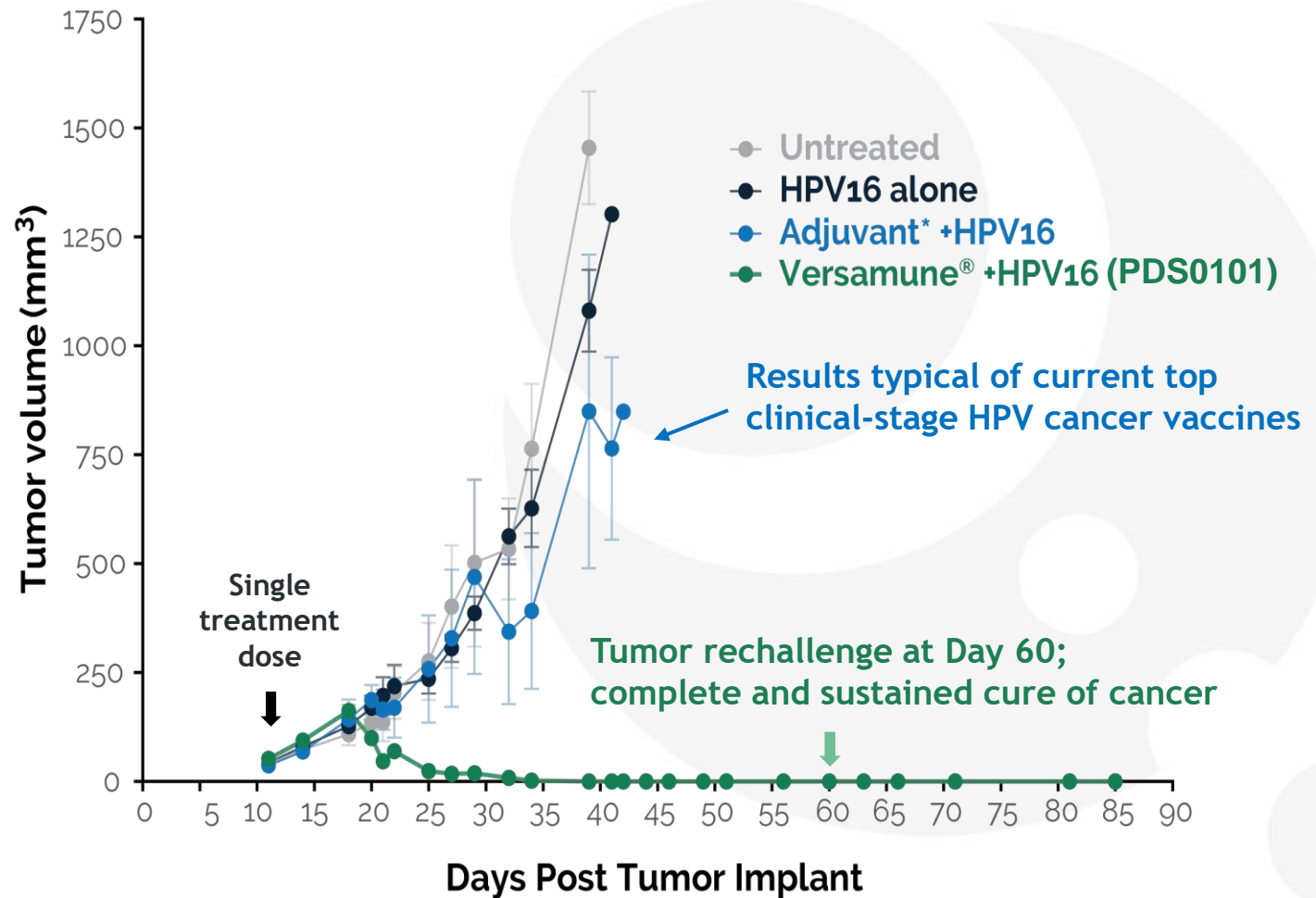
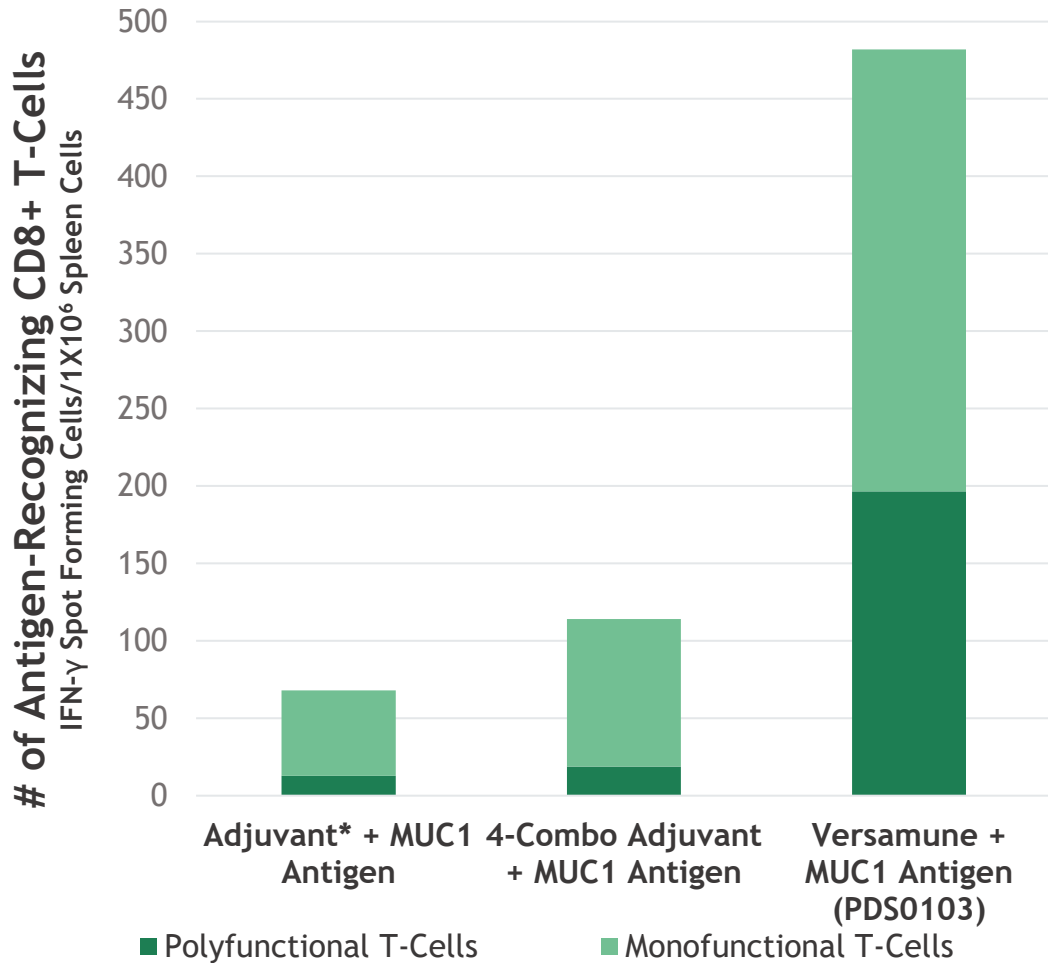
Promotes antigen processing and presentation to T-cells via MHC I and II pathways

Activates Type I Interferon pathway, enabling a powerful anti-tumor killer CD8+ T-cell response



# Greater quantity and quality of Versamune<sup>®</sup>-induced killer T-cells may result in unique ability to eradicate HPV-positive tumors after a single dose

Induced a >10-fold number of highly potent T-cells and eradication of HPV-positive tumors after a single dose in preclinical studies



A 3D molecular model of a protein structure. The central part is a large, dense cluster of grey spheres, representing a protein subunit or a complex. Several smaller, distinct clusters of red spheres are scattered around the main structure, likely representing ligands or other interacting molecules. The background is a dark, gradient blue.

# **PDS0101 Phase 2 Clinical Development**

# Clinical strategy: Develop PDS0101 in combination with established therapies for rapid proof-of-concept and risk mitigation

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## Combinations of PDS0101 with FDA-approved standard of care

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- ***First line treatment of recurrent/metastatic HPV-positive head and neck cancer***
  - Combination with Keytruda®
- ***Treatment of advanced localized cervical cancer***
  - Combination with chemoradiotherapy

## Novel combinations of PDS0101 with promising, investigational immunotherapeutic agents

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- ***Treatment of advanced HPV-associated cancers (anal, cervical, vaginal, head and neck etc.)***
  - Triple combination with Bintrafusp-alpha (bi-functional checkpoint inhibitor - M7824) and M9241 (antibody conjugated immunocytokine)

# Phase 2 investigator-led clinical trial evaluating the combination of PDS0101, M7824 and NHS-IL12 in advanced HPV-associated cancer

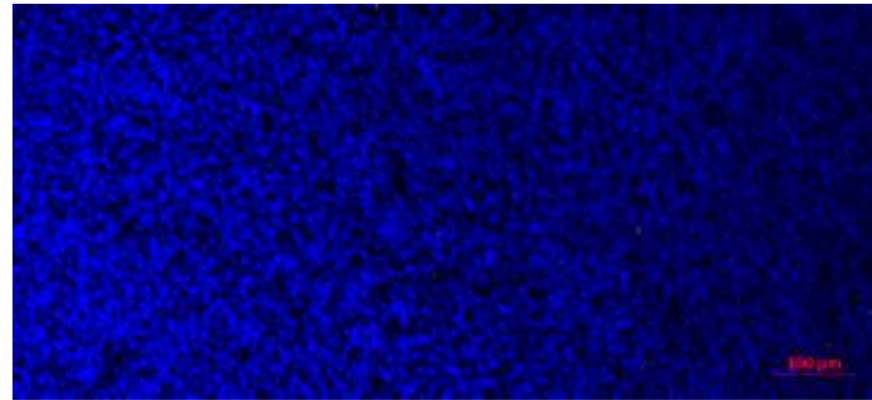
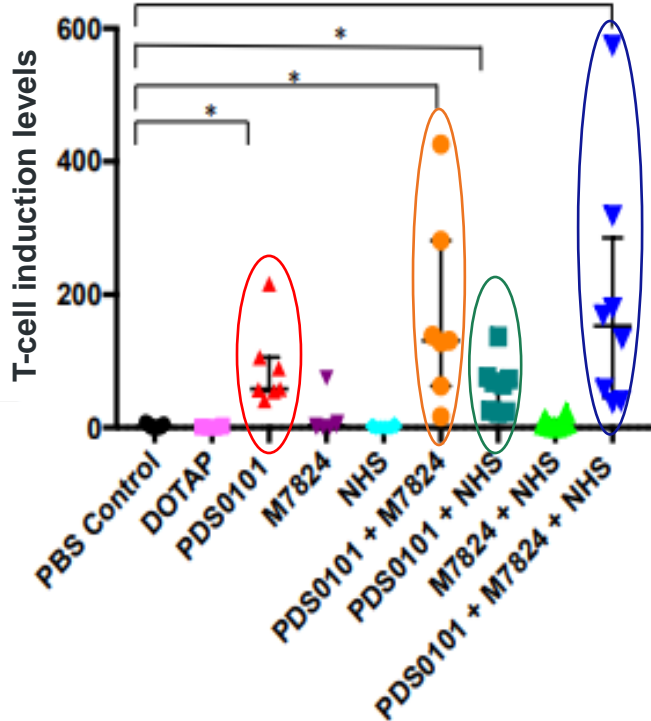
<b>Indication</b>	Patients with advanced HPV-associated cancer who have failed prior treatment
<b>Clinical Agents</b>	<b>Bintrafusp alfa (M7824):</b> Bifunctional “trap” fusion protein <b>M9241 (NHS-IL12):</b> Antibody-conjugated immuno-cytokine <b>PDS0101:</b> Versamune®-based immunotherapy generating HPV-specific CD8+ T-cells
<b>Study goals</b>	Group 1: Objective response rate (ORR) in <u>checkpoint inhibitor (CPI) naïve</u> patients Group 2: ORR in patients who have <u>failed checkpoint inhibitor therapy (CPI refractory)</u>
<b>Timing</b>	<b>Full enrollment of 45 patients triggered following achievement of objective response in <math>\geq 3</math> checkpoint inhibitor naive patients</b> <b>Trial completion expected in Q1 2022</b>
<b>Trial Sponsor</b>	

The objective of this trial is to confirm that PDS0101 enhances the therapeutic benefit of M7824 & NHS IL-12 and may lead to expanded evaluation in several cancers with PDS0102-0104

# Preclinical study: Triple combination of PDS0101, bintrafusp alfa and M9241 demonstrated higher level of efficacy than bintrafusp alfa monotherapy

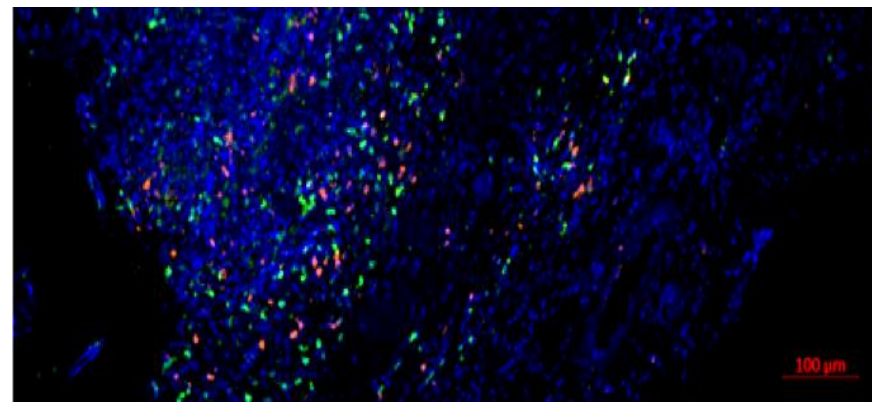
*Combination of PDS0101 with M9241 or Bintrafusp alfa generated superior targeted T-cell response; triple combination demonstrated superior efficacy*

HPV 16



**Bintrafusp alfa** (M7824 - bi-functional checkpoint inhibitor)

Tumor Regression: 0/16 (0%)  
T-cell Clones: 22



**PDS0101 + Bintrafusp alfa + M9241** (NHH IL-12)

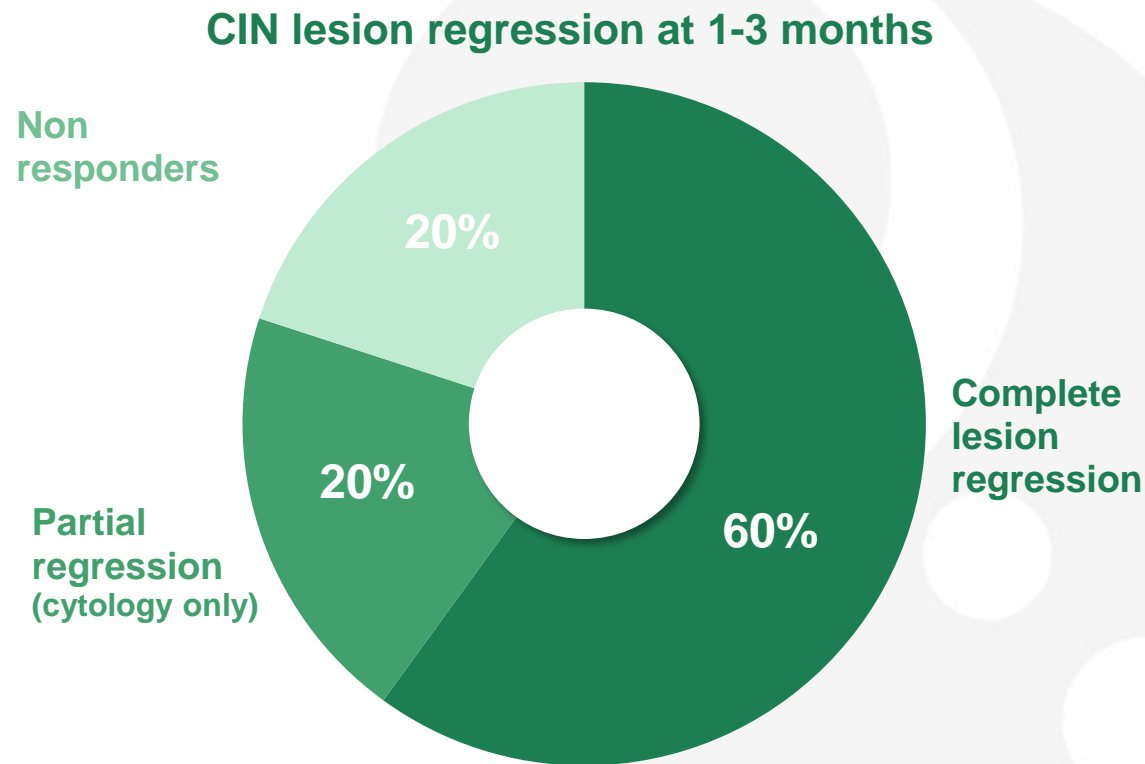
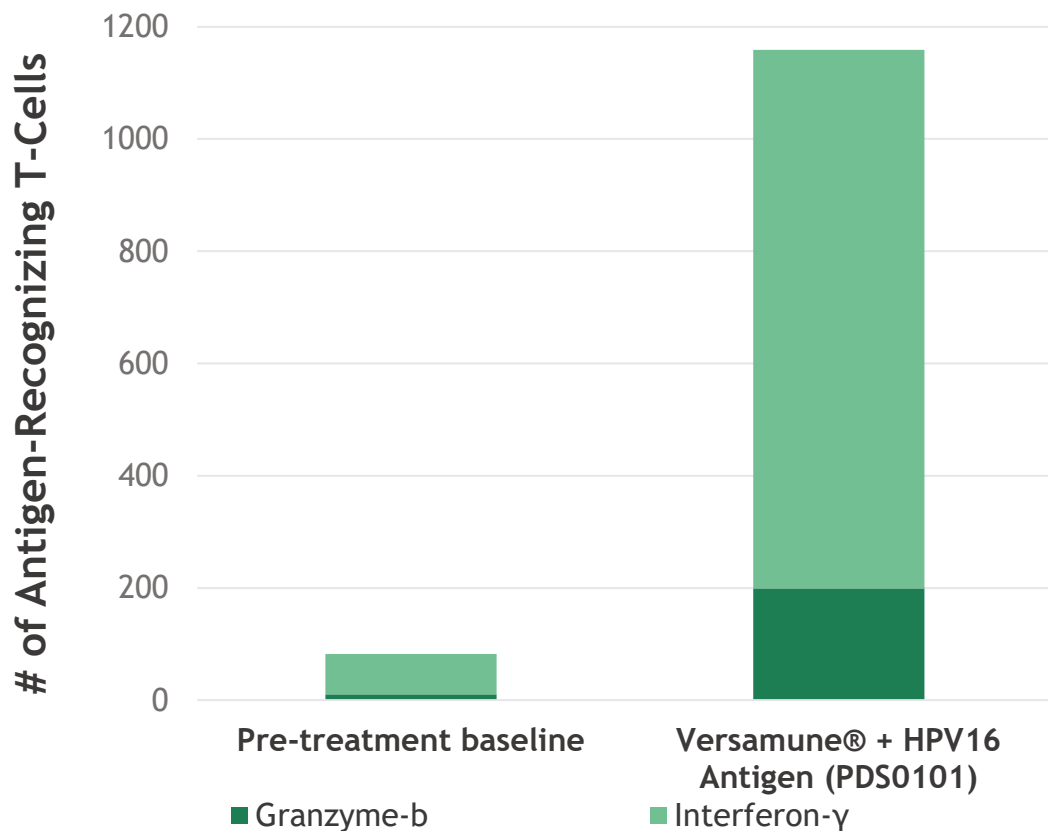
Tumor Regression: 13/17 (76%)  
T-cell Clones: 3

T-cell clones per 25% of TCR repertoire (Average)

Red – CD8+ (killer) T-cells  
Green – CD4+ (helper) T-cells

# PDS0101 Phase 1 clinical trial: Powerful CD8+ T-cell response resulted in regression of CIN cervical lesions & supported continued clinical studies

**Monotherapy overcomes key limitation of immuno-oncology: > 20-fold increase in circulating dual INF-γ & Granzyme-b inducing killer T-cells vs. pre-treatment at day 14 led to rapid clearance of lesions\***



Most patients infected with multiple strains of HPV

**Phase 1 trial results showed no serious or dose-limiting toxicities of PDS0101 monotherapy**

# PDS0101 phase 2 triple combination trial: Evaluated potential for superior preclinical tumor regression in advanced HPV-related cancer

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- Objective response rate is measured by RESCIST 1.1 and represents at least a 30% reduction in tumor size
- Advanced recurrent/refractory HPV-related cancer that is checkpoint inhibitor naïve:
  - Patients who fail chemotherapy and/or radiation progress to checkpoint inhibitor therapy
  - 12-24% ORR with standard of care checkpoint inhibitors
  - 30% ORR reported by experimental therapy Bintrafusp alfa is the highest reported to date
- Advanced recurrent/refractory HPV-related cancer that is checkpoint inhibitor refractory:
  - Few treatment options exist for these patients
  - 5-12% ORR reported with checkpoint inhibitors

***The most critical limitation of immunotherapy is the inability to induce large numbers of powerful tumor-attacking CD8+ (killer) T-cells within the body, that can result in tumor reduction or elimination in a significant number of advanced cancer patients***

# Triple combination achieved 83% ORR among 6 HPV16-positive patients

Checkpoint inhibitor naïve patients who failed both chemotherapy and/or radiation treatment

	HPV16 positive subjects	Current Standard of Care (Checkpoint Inhibitors)
Number of subjects	6	
Number of objective responses (tumor reduction)	5	
<b>Percentage of objective responses</b>	<b>83%</b>	<b>12-24%</b>

- Tumor types represented in checkpoint inhibitor naïve study arm include anal, cervical, head and neck and vaginal

**Preliminary results suggest PDS0101 induction of *in-vivo* tumor-attacking HPV16 killer (CD8+) T-cells may result in effective targeting of the HPV16-positive tumors resulting in disease reduction**

\* These numbers reflect data as of evaluation of 14 patients; numbers will change as more patients undergo evaluation



# Triple combination achieved 63% ORR among 8 HPV16-positive checkpoint inhibitor refractory patients

Patients who failed chemotherapy, radiation and checkpoint inhibitor therapy

	HPV16 positive subjects	Current Standard of Care (Checkpoint Inhibitors)
Number of subjects	8	
Number of objective responses (tumor reduction)	5	
<b>Percentage of objective responses</b>	<b>63%</b>	<b>5-12%</b>

- Tumor types represented in checkpoint inhibitor naïve study arm include anal, cervical, head and neck and vulvar

**Preliminary results suggest the triple combination may provide superior efficacy over checkpoint inhibitor monotherapy, even in immunologically limited patients**

\* These numbers reflect data as of evaluation of 14 patients; numbers will change as more patients undergo evaluation

# PDS Biotech-sponsored phase 2 trial evaluating the combination of PDS0101 and KEYTRUDA for first-line treatment of HPV-associated metastatic/recurrent head and neck cancer

**Indication** First line treatment of patients with HPV-associated head and neck cancer whose cancer has spread or returned

**Clinical Agents** **KEYTRUDA (Standard of Care):** Anti-PD1 checkpoint inhibitor (ORR ~20%)  
**PDS0101:** Versamune<sup>®</sup>-based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells

**Study goals** Objective response rate (ORR) and overall survival (OS)

**Timing** Preliminary data – Q4 2021/Q1 2022, ORR in first 20 patients (efficacy in 7 of 38 required to enroll all 96 patients)

**Trial Partner** 

If achieved, confirmation that PDS0101 enhances the therapeutic benefit of checkpoint inhibitors could expand evaluation of Versamune<sup>®</sup>-based therapies in multiple cancer indications

# A Phase 2, investigator-initiated clinical trial evaluating PDS0101 in combination with chemoradiation therapy in patients with advanced cervical cancer

<b>Indication</b>	Treatment of patients with locally advanced cervical cancer – Stages IB3-IVA
<b>Clinical Agents</b>	<b>Chemoradiotherapy (CRT – Standard of Care):</b> Cisplatin & radiation therapy <b>PDS0101:</b> Versamune <sup>®</sup> -based immunotherapy generating HPV-specific CD8+ and CD4+ T-cells
<b>Study goals</b>	Rate of regression in patients with primary tumor ≥5cm
<b>Timing</b>	Preliminary data – Q4 2021/Q1 2022 – Rate of complete response by PET-CT at 6 months and rate of tumor volume reduction by MRI at 30-40 days from start of treatment
<b>Trial Sponsor</b>	<small>THE UNIVERSITY OF TEXAS</small> <b>MDAnderson</b> <del>Cancer</del> Center

If successful, this study could support further investigation of Versamune<sup>®</sup>-based immunotherapies in combination with chemotherapy or CRT to treat multiple cancers

# Studies are designed to demonstrate efficacy and broad applicability of PDS0101 and the Versamune<sup>®</sup> T-cell activating platform

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***Potential to treat all types of HPV-cancer:*** PDS0101 Phase 2 clinical studies address all types of HPV-associated cancers.

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***Potential to enhance anti-cancer efficacy of various cancer treatments:*** Combinations with checkpoint inhibitors, chemotherapy and novel therapies may demonstrate Versamune<sup>®</sup>'s versatility.

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***Potential applications beyond oncology:*** PDS0203 COVID-19 phase 1/2 trials may demonstrate protection and induce durable T-cell responses against conserved regions of mutating viruses.

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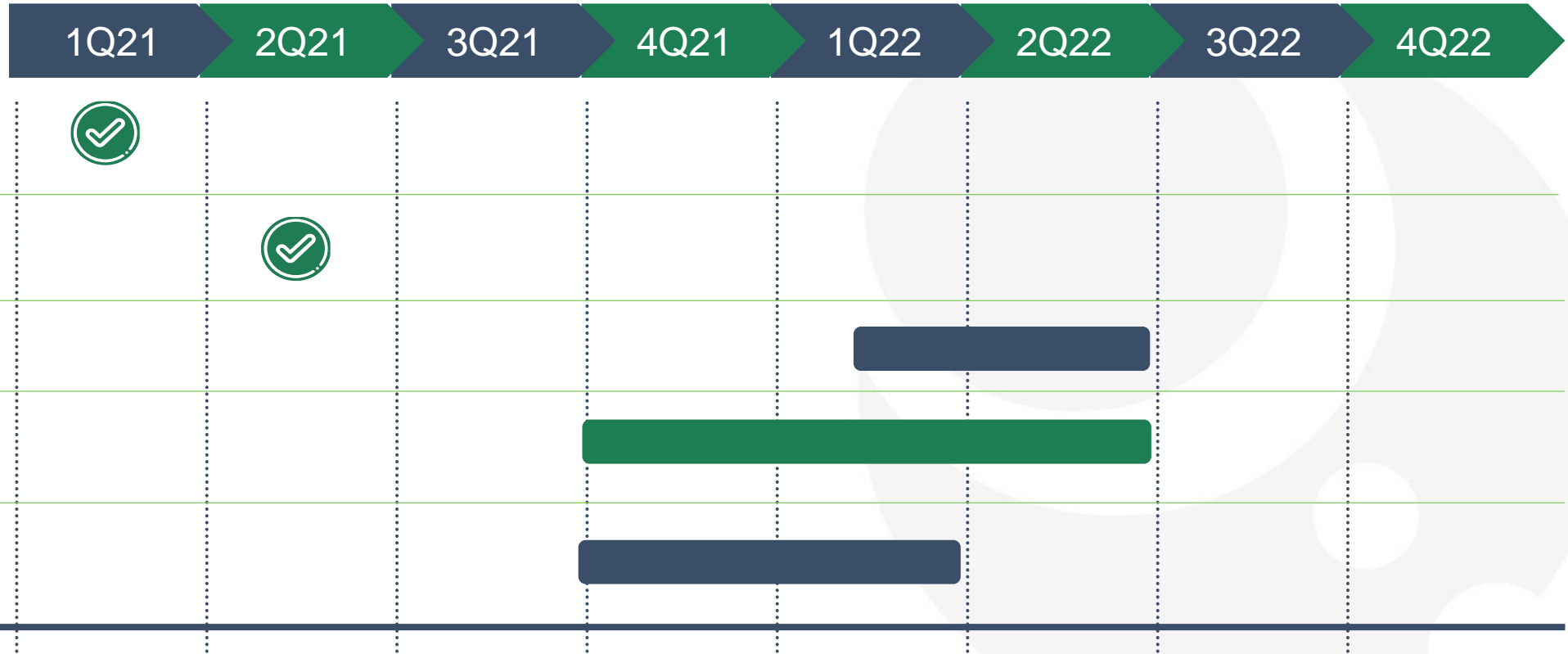
***Broad potential for additional partnerships:*** Successful phase 2 studies with PDS0101 and PDS0203 could enable a broad pipeline of Versamune<sup>®</sup>-based products containing various antigens.



# **PDS0101 Near-term Milestones & Market Opportunities**

# Projected PDS0101 milestones through 2022\*

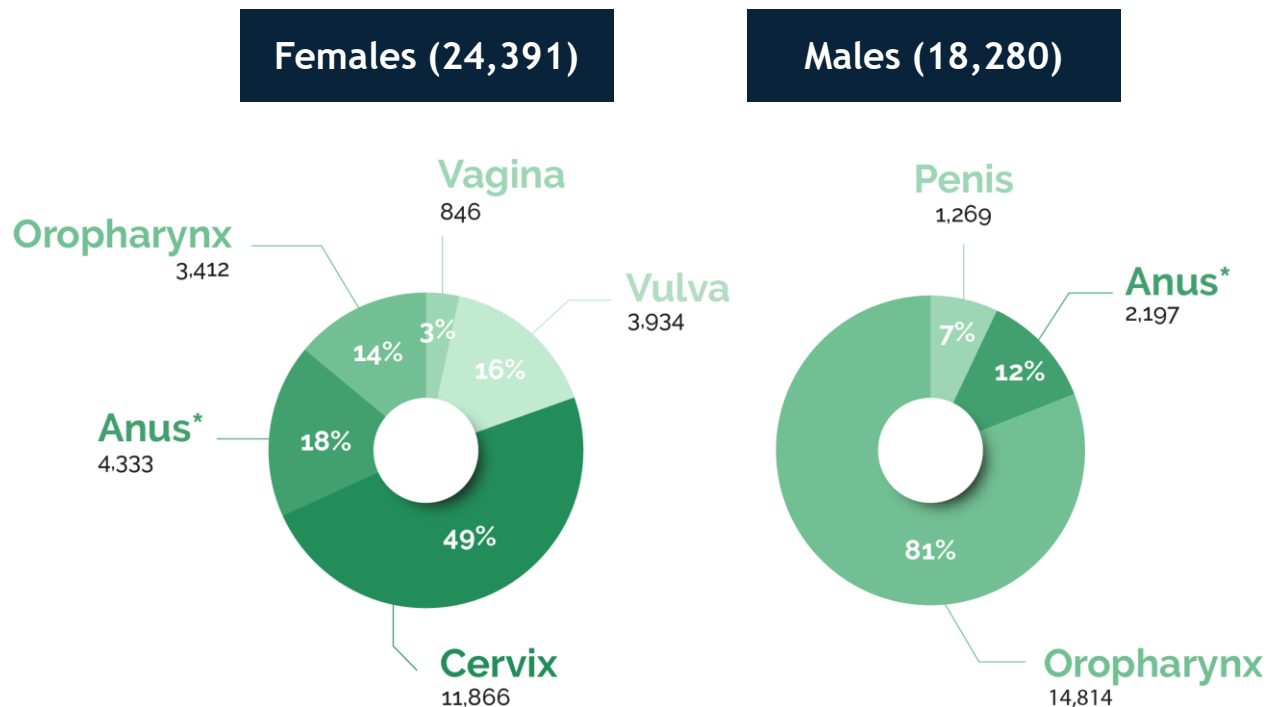
- PDS Biotech Funded Clinical Trials
- Partner Co-Funded Clinical Trials



PDS0101

# PDS0101 is designed to treat cancers caused by human papillomavirus (HPV)-16, which represents 70-80% of the HPV-associated cancer market

## US annual HPV-associated cancer incidence<sup>1</sup>



- Approximately 43,000 patients are diagnosed with HPV-associated cancers annually in the US<sup>1</sup>
- Existing immunotherapies cost \$120,000+ annually per patient<sup>2</sup>
- Incidence rate is growing and remains a significant unmet medical need

## Versamune® has demonstrated the potential for immunological compatibility with a wide array of tumor and pathogenic antigens

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- Versamune®'s unique flexibility means it may work well with a wide range of identified tumor and infectious disease antigens
  - **4 tumor antigens** are currently being utilized with the Versamune® platform
    - PDS0102 (TARP) for the treatment of AML, prostate and breast cancer
    - PDS0103 (MUC1) for the treatment of breast, colorectal, ovarian and non-small cell lung cancer
    - PDS0104 (TRP2) for the treatment of melanoma
  - Over **70 tumor antigens** have been identified to date
- Proof of concept data from ongoing clinical trials could trigger development activities for Versamune®-based products through partnerships and licensing



# PDS Biotech's robust Versamune<sup>®</sup>-based oncology pipeline is being developed in partnership with the leaders in immuno-oncology

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<u>PDS0104 (TRP2)</u>	Melanoma	TBD	PDS Biotech Funded					

PDS Biotech Funded



Partner Co-Funded





**Farmacore License Agreement  
for Versamune<sup>®</sup>-Based  
COVID Vaccine**

# Development of PDS0203, if successful, may offer potential advantages as a second generation COVID-19 vaccine

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## May be effective against multiple COVID-19 variants

Demonstrated induction of killer CD8+ and helper CD4+ T cells that can target **less variable regions** of the SARS-CoV-19 virus and may be effective against currently circulating variants.



## May grant long-lasting immunity

Demonstrated induction of **long-lasting, virus-specific memory T-cells** necessary for longer term protection.



## High potential for safety

PDS0203 is a subunit vaccine, and does not require the use of attenuated viruses, traditional adjuvants, DNA or RNA. Versamune<sup>®</sup>-based vaccines have shown **no serious or dose limiting reactions**.

# PDS0203, if development is successful, could offer another option to address the COVID-19 global health crisis

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- Consortium has received a commitment of up to ~US\$60 million from MCTI, Brazil to support phase 1-3 clinical development and manufacturing scale-up
  - PDS Biotech has licensed Versamune<sup>®</sup> technology to Farmacore to develop a COVID-19 vaccine candidate
  - Farmacore is responsible for antigen manufacturing and clinical development
- Phase 1/2 study anticipated to start following Farmacore's submission of a full data package to and subsequent approval from Anvisa (Brazilian regulatory agency)
- PDS Biotech is closely monitoring the evolving political situation in Brazil as which may result in potential challenges to developing a Versamune<sup>®</sup>-based COVID-19 vaccine
  - Intellectual property protections for a Versamune-based COVID-19 vaccine potentially at risk
    - Brazil's senate has voted for compulsory licensing for COVID-19 vaccine technology
    - Legislative process is ongoing
  - Funding release is subject to negotiations among Farmacore, MCTI, and Brazilian authorities

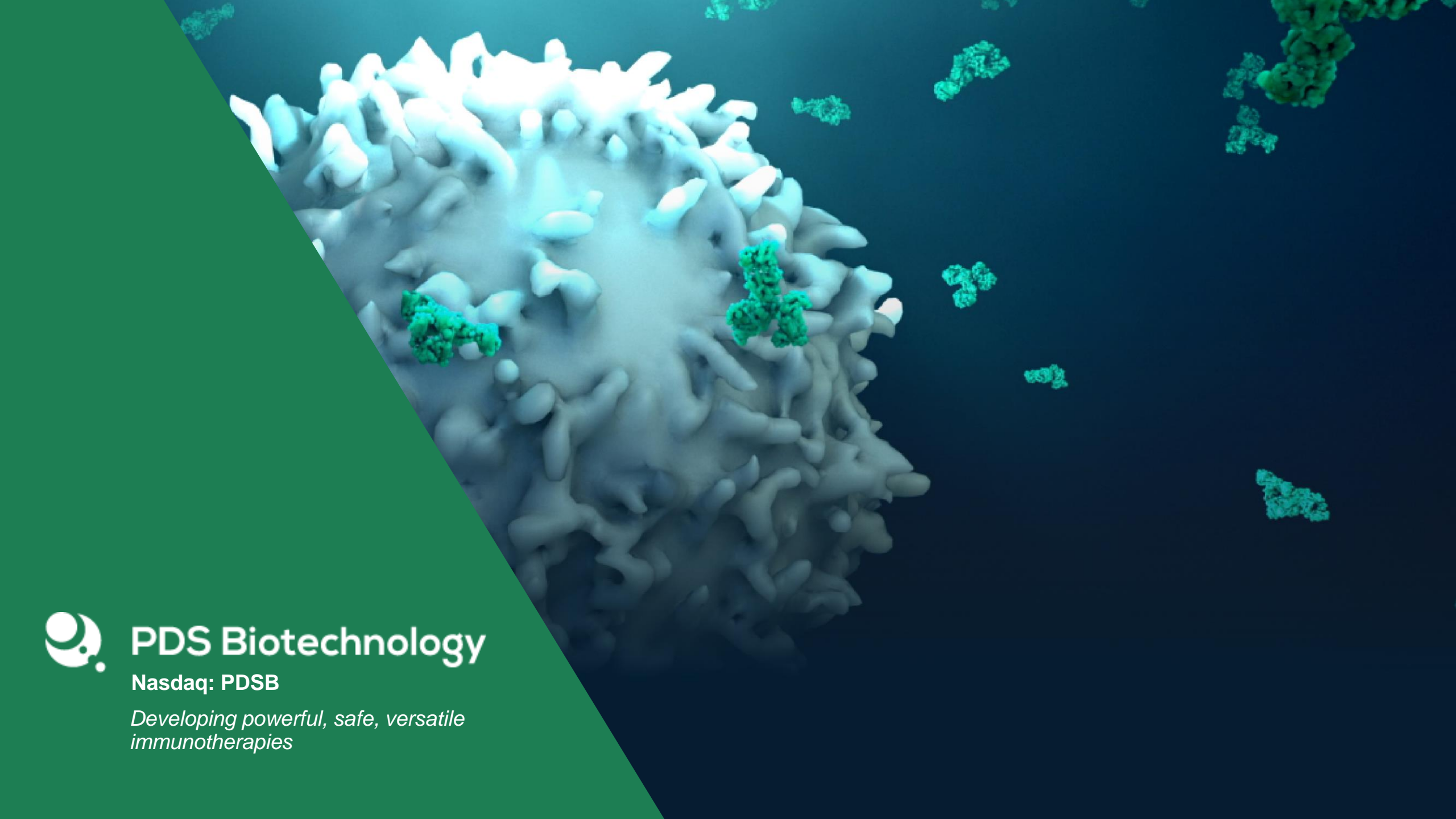


# Final Comments

# Rapid commercialization strategy

## Potential Advantages and Differentiators

- **Promising early data in both oncology and infectious disease:** Early clinical data and preclinical data suggest potential efficacy, safety and versatility of the Versamune® platform
- **Near-term milestones:** PDS0101 interim efficacy data presented at ASCO in NCI-led Phase 2; preliminary data from MD Anderson-led study and PDS Biotech-led VERSATILE-002 anticipated Q4 2021 - Q2 2022
- **Validation of approach:** All three on-going phase 2 clinical trials supported and partnered with leading and top-tier institutions in the field of cancer and immuno-oncology
- **Commercialization path:** Clinical studies demonstrating enhancement of FDA-approved anti-cancer products may offer potential for expedited programs
- **Rapid adoption strategy:** Evaluation of PDS0101 in combination with standard of care in multiple HPV-associated cancers



# PDS Biotechnology

Nasdaq: PDSB

*Developing powerful, safe, versatile immunotherapies*