



# CORPORATE OVERVIEW

OCTOBER 2020



**PDS Biotechnology**

*A new generation of multi-functional  
cancer immunotherapies*

**Frank Bedu-Addo Ph.D.** President & CEO



## 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.

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

## CORPORATE OVERVIEW

- Mid-clinical stage biopharma developing novel treatments for cancer and novel T-cell activating infectious disease vaccines
- Publicly listed on NASDAQ: PDSB
- ~15 employees with headquarters in Florham Park and Princeton, NJ
- Approximately \$34.0M in cash\*

## VERSAMUNE<sup>®</sup> PLATFORM

- Versatile and potent T-cell-activating platform
- Clinically supported induction of active antigen-specific killer and helper T-cells *in vivo*
- Promising clinical efficacy demonstrated in early trials of PDS0101 monotherapy with favorable safety profile and no dose limiting toxicities

# PDS Biotech's pipeline combines the Versamune® platform with proprietary antigens across 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®	PDS Biotech Funded					MERCK
<u>PDS0101 (HPV16)</u>	Advanced HPV-associated malignancies	M7824 NHS-IL12	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>	Prostate and Breast Cancer	Immunotherapy	PDS Biotech Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0103 (MUC-1)</u>	Breast, Colorectal, Ovarian and NSCLC Cancer	Immunotherapy	PDS Biotech Funded					NIH NATIONAL CANCER INSTITUTE
<u>PDS0104 (TRP2)</u>	Melanoma	Immunotherapy	PDS Biotech Funded					
<b>Infectious Disease</b>								
<u>PDS0201 (M-tuberculosis)</u>	Prevention of tuberculosis		PDS Biotech Funded					Farma core
<u>PDS0202 (influenza)</u>	Universal prevention of influenza		PDS Biotech Funded					NIH National Institute of Allergy and Infectious Diseases
<u>PDS0203 (SARS-CoV-2)</u>	Prevention of COVID-19		PDS Biotech Funded					
<u>PDS0204 (SARS-CoV-2FC)</u>	Prevention of COVID-19		PDS Biotech Funded					Farma core

PDS Biotech Funded  Partner Co-Funded 

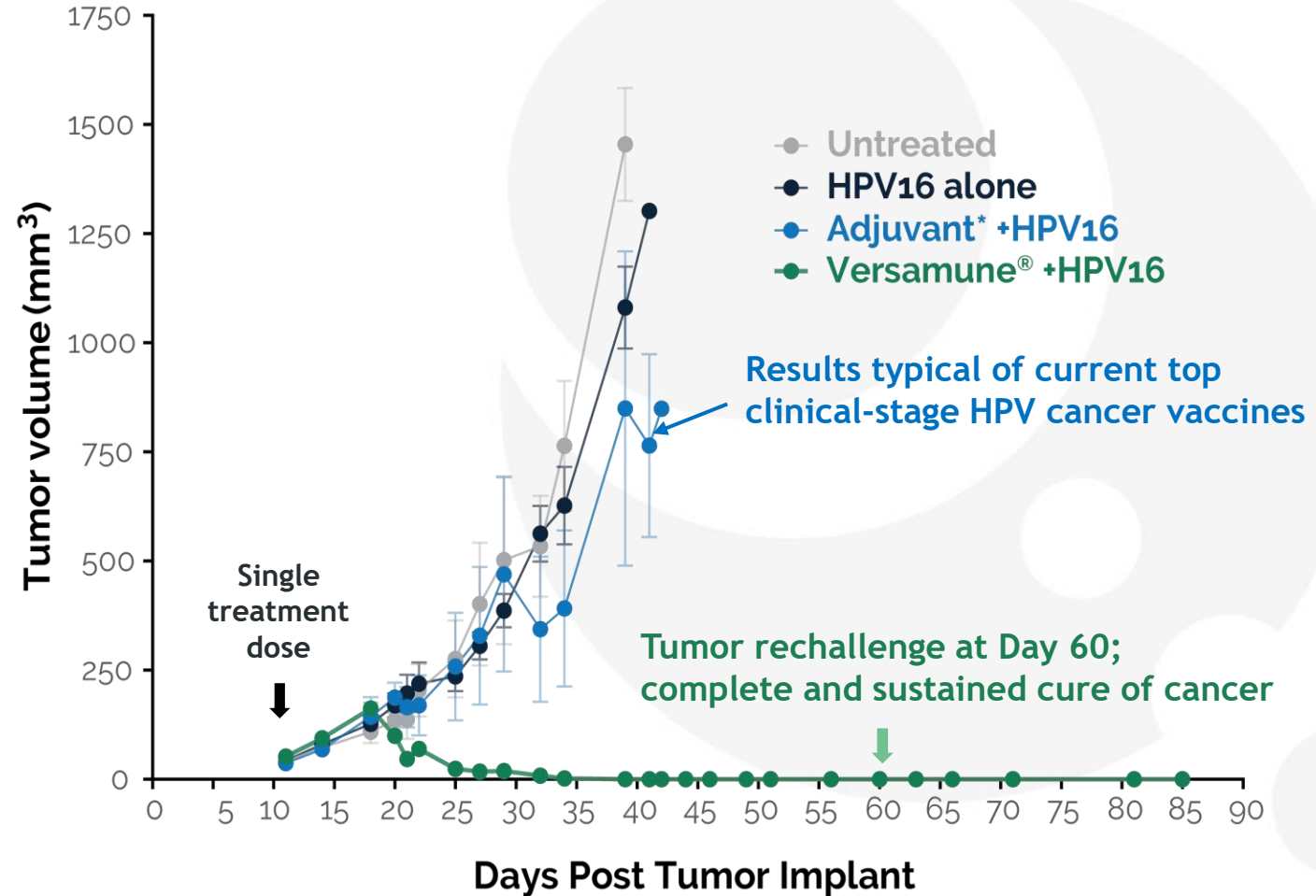
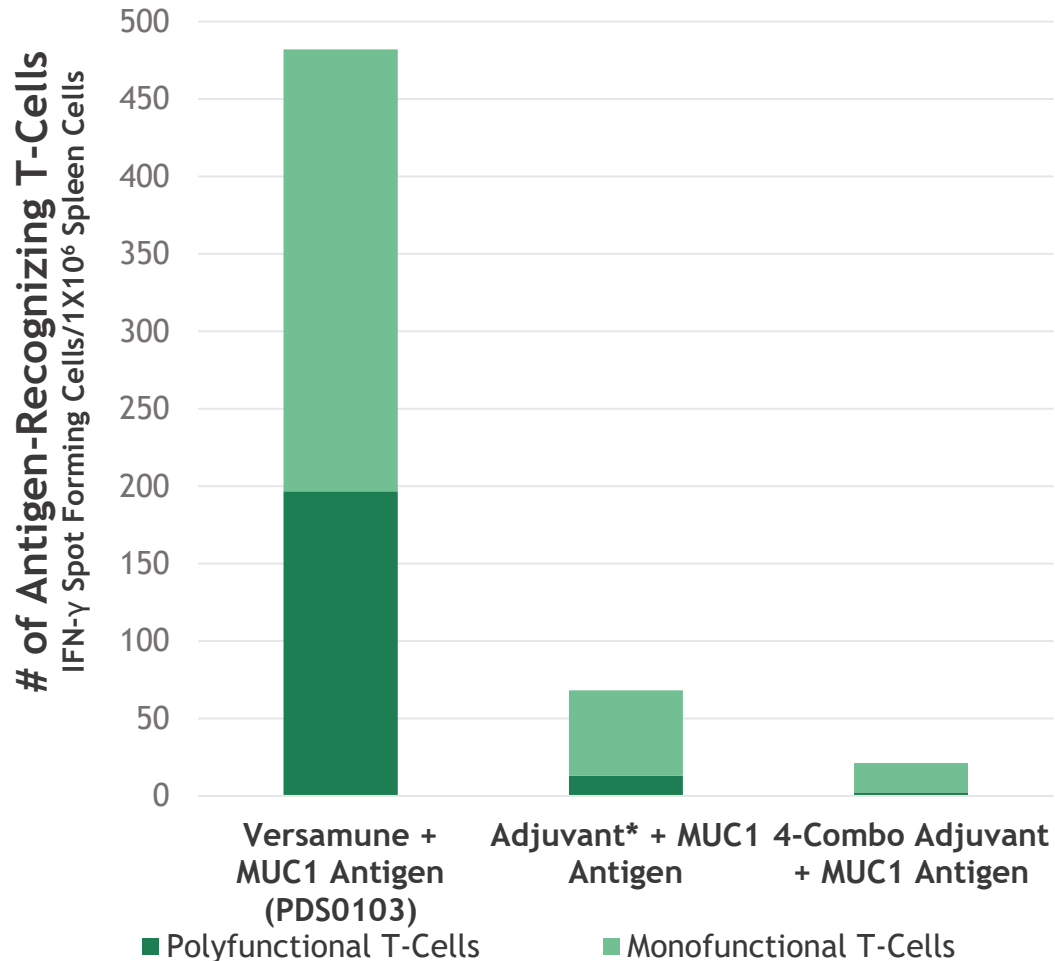
A 3D scientific illustration of a spherical virus particle. The surface is covered in numerous small, light blue, spike-like proteins. Several larger, green, Y-shaped structures, representing antibodies, are shown binding to the surface proteins. The background is a dark blue gradient.

# Versamune<sup>®</sup> Platform



# 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

*Produces > 10-fold number of highly potent (polyfunctional) killer T-cells vs. other T-cell technologies*



# Versamune® uniquely possesses the important characteristics of a safe and effective immunotherapeutic treatment

	Versamune®
Access to lymph nodes	✓
Induction of high levels of polyfunctional CD8+ (killer) T-cells	✓
Induction of high levels of polyfunctional CD4+ (helper) T-cells	✓
Ability to overcome tumor immune suppression	✓
Induction of long-term memory T-cells	✓
Low systemic toxicity risk	✓

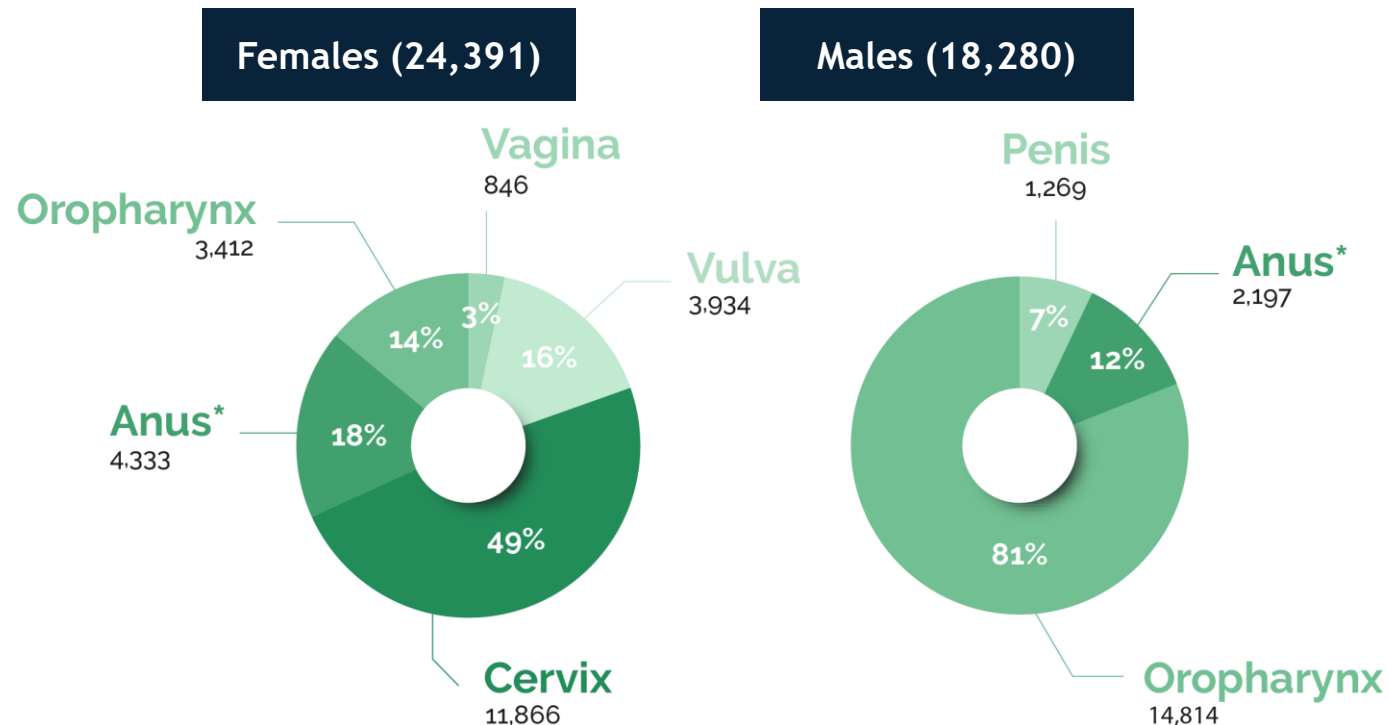


A 3D molecular model of a cell surface receptor, likely a G-protein-coupled receptor (GPCR), shown in a light blue/white color. The receptor is embedded in a lipid bilayer, which is rendered in a darker blue. Several green, Y-shaped or cross-shaped molecules, representing ligands, are bound to the extracellular side of the receptor. The background is a dark blue gradient.

# Oncology: PDS0101 Clinical Development

# PDS0101 is designed to treat cancers caused by human papillomavirus (HPV)

Approximately 43,000 patients are diagnosed with HPV-associated cancers each year, a number unlikely to be impacted by increased use of HPV preventive vaccines in the next decade

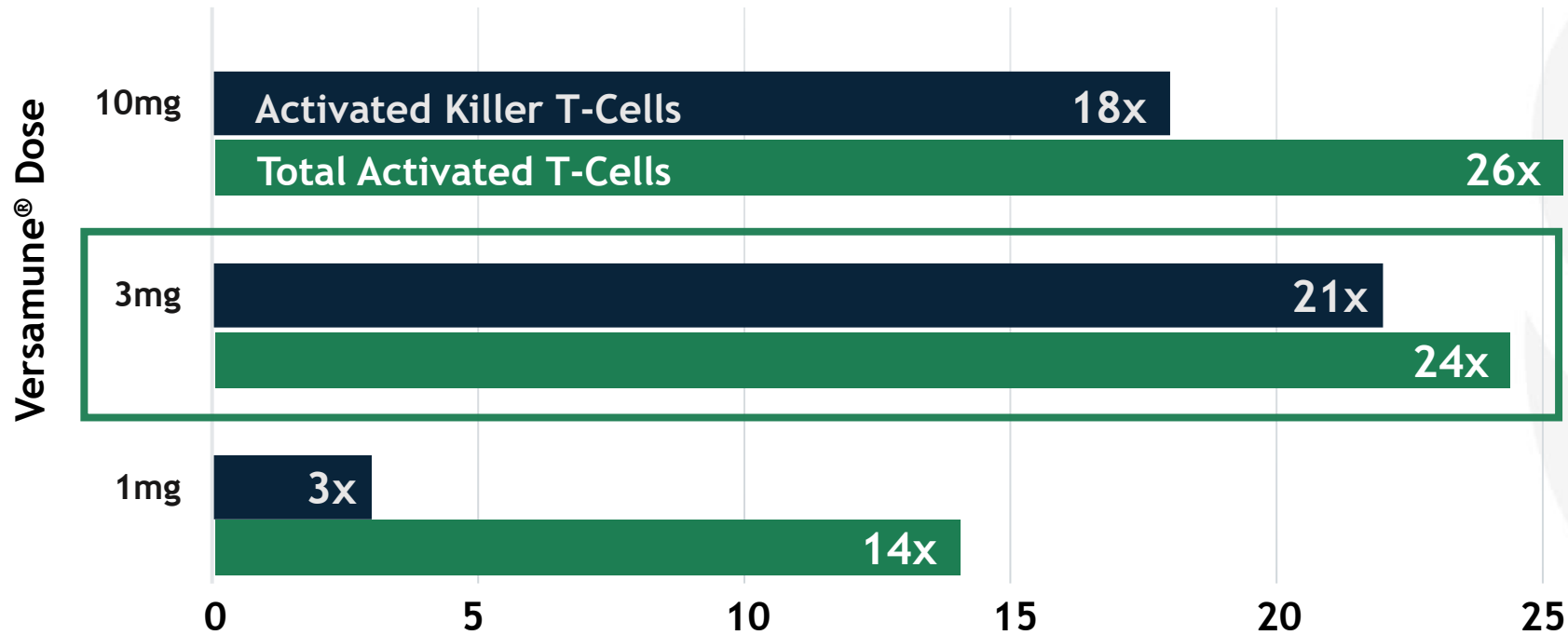


- **Oropharyngeal (head & neck) cancers**
  - >18,000 cases annually
  - Most common HPV-cancer in men
  - **Incidence increasing**
- **Cervical cancer**
  - ~12,000 cases annually
  - Most common HPV-cancer in women
  - Incidence steady
- **Initial market research suggests PDS0101 market penetration of ~20% is a conservative estimate**

PDS0101 combines the utility of the Versamune® platform with a proprietary mix of HPV16 antigens, the most virulent high-risk HPV type and by far the most prevalent in patients with HPV-associated cancer

# PDS0101 Phase 1 clinical trial (monotherapy): Unique *in vivo* demonstration of high levels of HPV-specific killer T-cells in circulation

Clinical study results successfully demonstrate translation of Versamune®'s multi-functional mechanism of action from pre-clinical models to humans



Order of magnitude increase over baseline

■ INF-γ Elispot (Total active HPV-specific T-cells) ■ Granzyme-b Elispot (Active HPV-specific killer (CD8) T-cells)

## Clinical Study Results in Patients with CIN




- All high-risk HPV eligible
- 3 subcutaneous injections 3 weeks apart
- T-cell responses at Day 14
- Defined dose for Phase 2 oncology studies (3mg)
- No dose-limiting toxicities

# PDS0101 Phase 2 clinical strategy in advanced cancer: Focus on efficiency and risk mitigation to proof of concept

Versamune<sup>®</sup>-based immunotherapies are initially being studied in Phase 2 trials as combination therapies to enhance the clinical benefit of FDA-approved therapies that have been demonstrated to be safe, well tolerated and effective

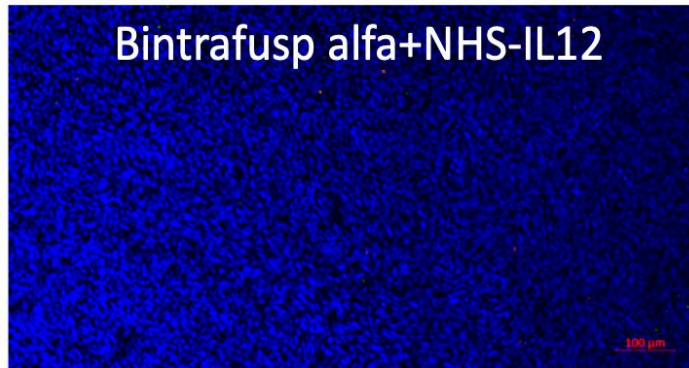
- Combinations with FDA-approved standard of care
  - **First line treatment of recurrent/metastatic HPV-positive head and neck cancer**
    - Combination with Keytruda<sup>®</sup>
  - **Treatment of advanced localized cervical cancer**
    - Combination with chemoradiotherapy
- Novel combinations with promising immunotherapeutic agents
  - **Treatment of advanced HPV-associated cancers** (anal, cervical, vaginal, head and neck etc.)
    - Triple combination with Bintrafusp-alpha (bi-functional checkpoint inhibitor - M7824) and NHS-IL12 (antibody conjugated immuno-cytokine)

# Phase 2 studies of PDS0101 in combination therapy will evaluate efficacy and safety in treatment of multiple advanced HPV cancers

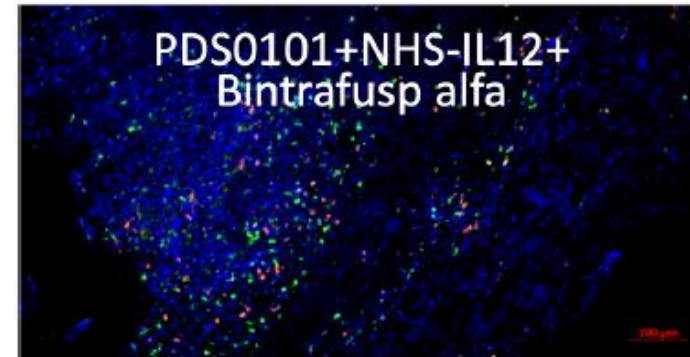
Partner	Phase 2 Open Label Study (Safety and Efficacy)	Important Considerations	Initiation
	<ul style="list-style-type: none"> <li>Advanced HPV-associated malignancies – all HPV types</li> <li>Combination with EMD Serono’s Bintrafusp-alfa (M7824) + NHS-IL12</li> <li>28 subjects</li> </ul>	<ul style="list-style-type: none"> <li>Preclinical confirmation of synergies with PDS0101</li> <li>All three agents have demonstrated potential efficacy as monotherapies in early trials</li> </ul>	<p><b>Initiated in June 2020</b></p>
	<ul style="list-style-type: none"> <li>Recurrent/metastatic HPV16-associated head &amp; neck cancer – First line</li> <li>Combination with Merck’s Keytruda®</li> <li>96 subjects</li> </ul>	<ul style="list-style-type: none"> <li>First line therapy unique for combination I-O</li> <li>Keytruda FDA-approved as first-line therapy for the target indication</li> </ul>	<p><b>Initiation planned Q4 2020</b></p>
	<ul style="list-style-type: none"> <li>Advanced, localized cervical cancer– all HPV types (Stage II-IVa)</li> <li>Combination with chemo-radiotherapy (CRT)</li> <li>35 subjects</li> </ul>	<ul style="list-style-type: none"> <li>T-cell induction has strong potential to enhance CRT efficacy</li> <li>Mitigated risk</li> <li>CRT is FDA-approved as therapy for the target indication</li> </ul>	<p><b>Initiation planned Q4 2020</b></p>

# Novel and unique triple combination including PDS0101 shows promising anti-tumor immune responses in highly aggressive tumor

Staining of HPV-positive tumors to identify infiltrated CD4+ and CD8+ T cells after treatment (preclinical study) – Results analogous to turning tumors from “cold” to “hot”



PDS0101 promotes enhanced T-cell induction and specificity vs. B-alfa + NHS-IL12\*



CD4 T-cells – Green  
CD8 T-cells – Red  
DAPI - Blue

PDS0101 promotes enhanced tumor regression \*



8 of 16 have tumor volumes less than 300mm<sup>3</sup>  
(0 of 16 in untreated group)

13 of 17 have tumor volumes less than 300mm<sup>3</sup>



# Infectious Disease

# Preclinical testing of Versamune<sup>®</sup>-based COVID-19 and universal influenza vaccine candidates ongoing with clear target profiles

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1

Induction of highly-potent, virus-specific killer (CD8) and helper (CD4) T-cells

2

Rapid induction high levels of neutralizing antibodies within 14 days

3

Simple, safe and effective subunit vaccines

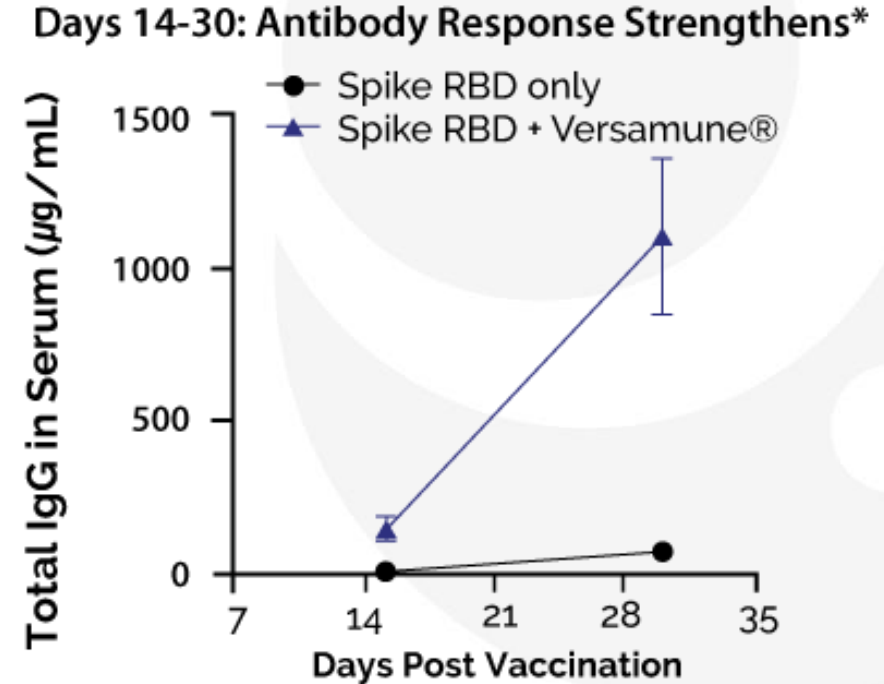
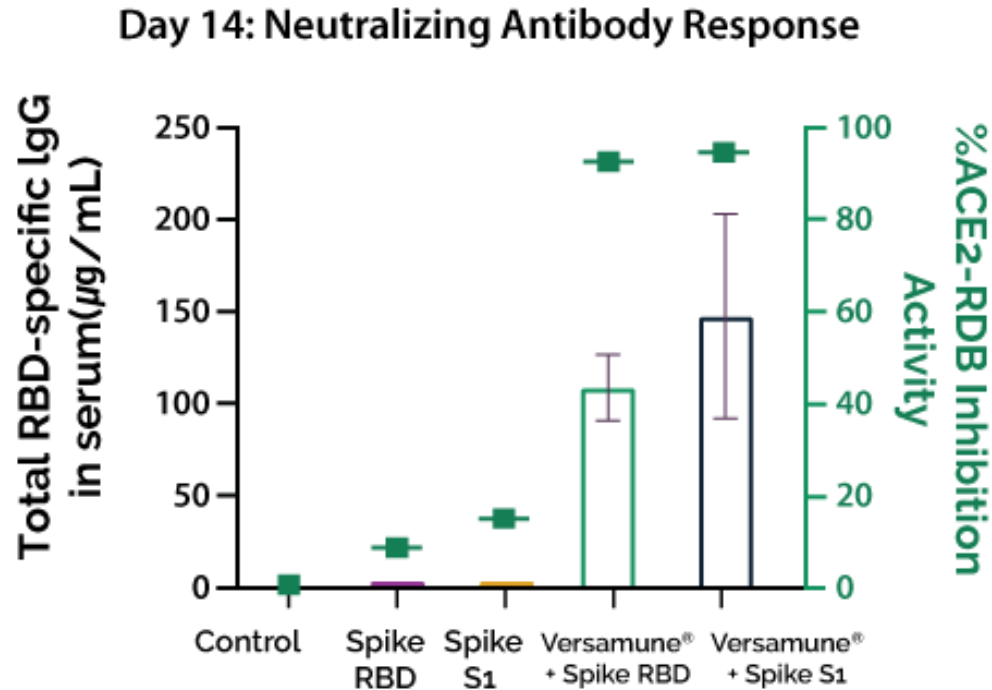
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Suitable for rapid commercial scale up



# PDS0203: Versamune<sup>®</sup>-based COVID-19 vaccine induced rapid and potent antibody responses to SARS-CoV-2 in two weeks

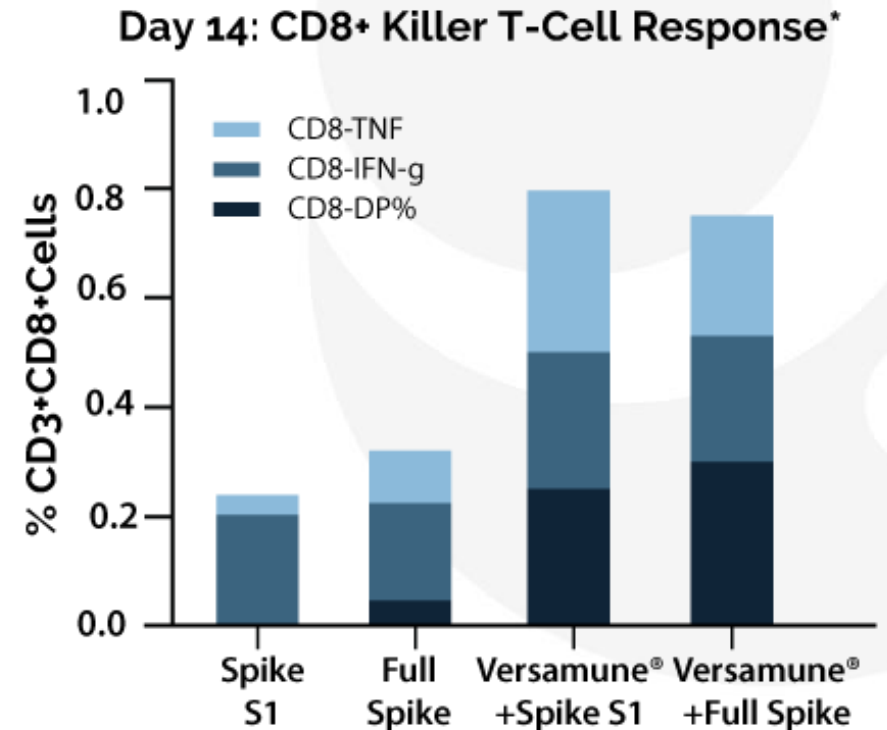
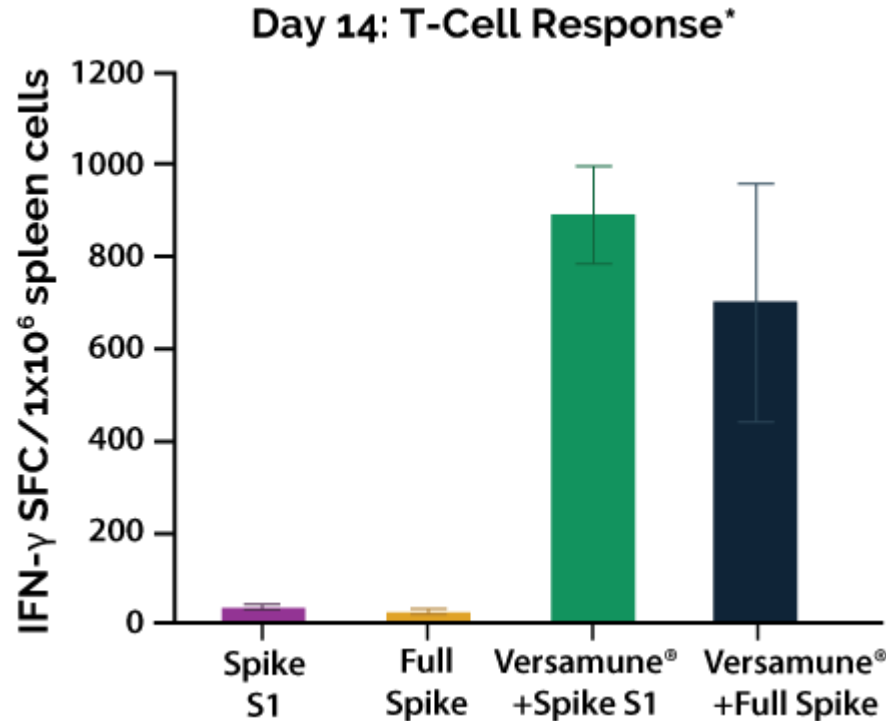
*Preclinical studies demonstrate that Versamune<sup>®</sup> + RBD\*\* and Versamune<sup>®</sup> + S1\*\* induce antibodies at a level equivalent to those observed in hospitalized COVID-19 patients within just 2 weeks of vaccination*



# PDS0203: Versamune<sup>®</sup>-based COVID vaccine uniquely induces strong T-cell responses against SARS-CoV-2 in two weeks

Preclinical data suggest Versamune<sup>®</sup> induces T-cells, including polyfunctional CD4+ (helper) & CD8+ (killer) T-cells, against SARS-CoV-2 - when combined with either the S1 domain or full Spike-protein

*Strong T-cell responses also confirmed at 60 days: Long-lasting (memory T-cells)*





# Intellectual Property and Financials

# Multiple layers of technology and product protection for Versamune<sup>®</sup>-related products through mid-2030s

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- Versamune<sup>®</sup> and associated patents are owned and licensed by PDS Biotech
- PDS-owned patents cover methods and compositions stimulating/promoting an immune response with Versamune<sup>®</sup> technology in various forms and mechanisms through 2034
  - Use of specific cationic lipids to induce an immune response
  - Compositions and use of any cationic lipid to activate MAP kinase
  - Compositions and use of R-DOTAP to induce immune response
  - Micellar antigen + cationic lipids compositions (US still ongoing)
  - Compositions of R-DOTAP with GM-CSF to reduce immune suppressive myeloid derived suppressor cells in the tumor
- Five issued international patent families (including Europe and Japan)

# Strong financial position to support near-term milestones

*Timing of 2020 milestones will be impacted by the COVID-19 pandemic*

Nasdaq	PDSB
Cash*	\$34.0M
Debt*	---

- ✓ PDS0101 (HPV): Initiation of NCI-led Phase 2 combination study in advanced HPV-associated cancers
- ✓ PDS0203 (SARS-CoV-2): Complete preclinical formulation development and feasibility testing
- PDS0101 (HPV): Initiation of MD Anderson-led Phase 2 combination study in advanced cervical-cancer
- PDS0101 (HPV): Initiation of VERSATILE-002 Phase 2 study of first line treatment of recurrent/ metastatic head and neck cancer in combination with KEYTRUDA®
- PDS0202 (influenza): Generate initial feasibility data on universal flu vaccine

# PDS Biotechnology 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)



## ■ 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



## ■ Michael King Chief Financial Officer (Interim)

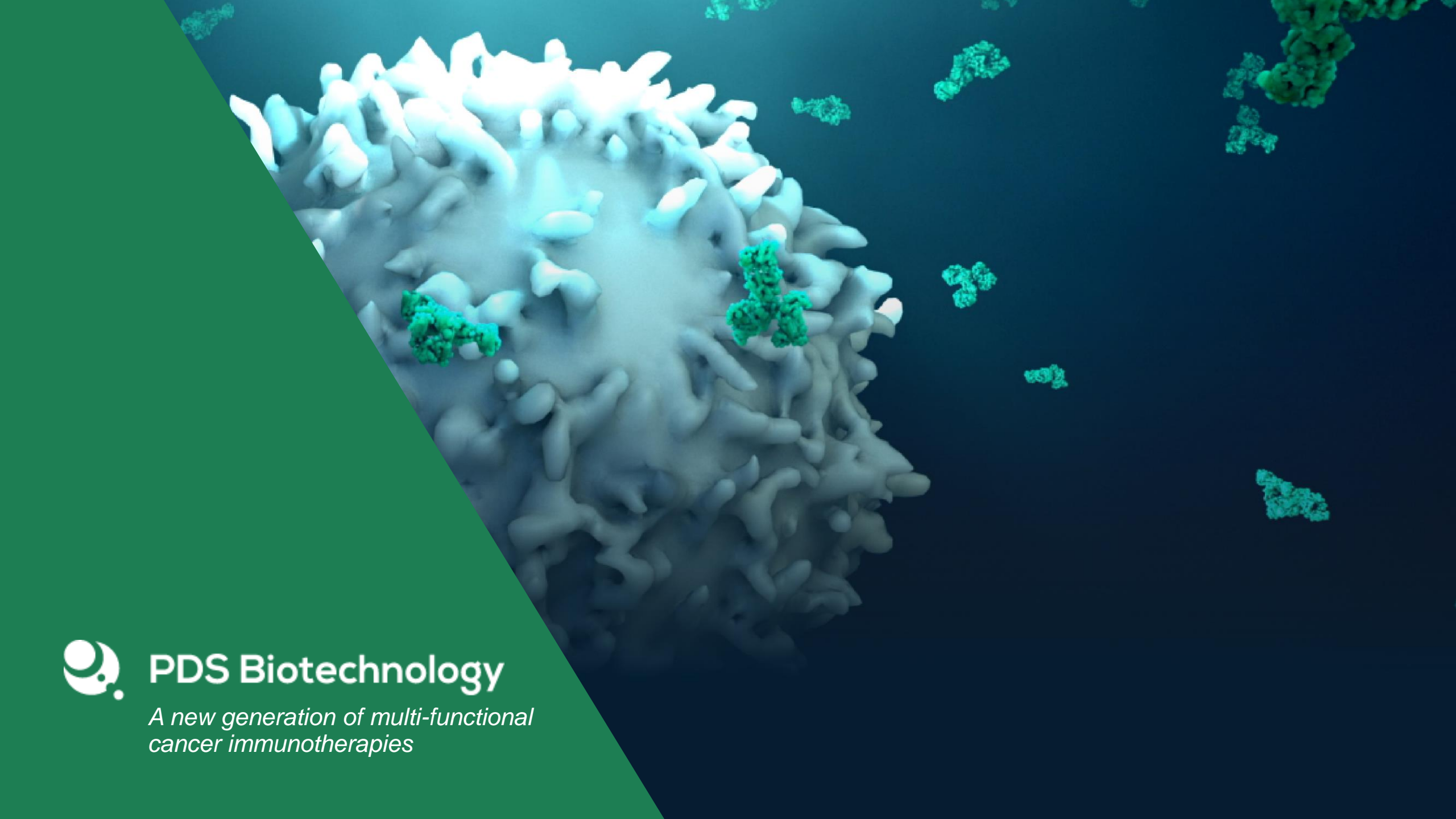
- Senior executive experience with over 20 years of experience in pharma and drug development
- In-depth experience with M&A transactions, capital markets, and investor relations



# PDS Biotech poised to transform vaccines and cancer treatment by fulfilling the promise of immunotherapy

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- 1 Powerful immunotherapy platform that activates therapeutic and preventive immunological pathways
- 2 Demonstrated potential for strong clinical efficacy and durability of response with minimal toxicity
- 3 Diversified pipeline focused on oncology and infectious disease
- 4 Clinical studies in areas of high unmet medical need supported by leaders in the field



**PDS Biotechnology**

*A new generation of multi-functional  
cancer immunotherapies*