



*A new generation of multi-functional  
cancer immunotherapies*

**Corporate Presentation**

**September 2019**

**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 preclinical 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, PDS undertakes no obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

# Investment Highlights

## PDS Biotechnology

- Clinical stage biotechnology company developing pipeline of novel cancer immunotherapies based on proprietary Versamune<sup>®</sup> platform

## Versamune<sup>®</sup> Platform

- Versatile T-cell-activating platform developed to treat early- & late-stage cancers
- Early clinical data and preclinical studies suggest potential for best-in-class combination of potency and safety
- Strong induction of CD8+ and CD4+ T-cells demonstrated in Phase 1 study

## Product Pipeline

- Lead program PDS0101 targeting multiple indications in >\$6 billion HPV cancer market e.g. head and neck cancer, anal, cervical, CIN2/3\*
- PDS0101 clinical studies projected to initiate in 1Q 2020
  - Phase 2b CIN 2/3 monotherapy study
  - Phase 2 combination therapy with KEYTRUDA<sup>®</sup> in head and neck cancer
- Pipeline includes melanoma, prostate, breast, colon, lung cancers

# Current State of Immuno-Oncology (I-O)

## The Promise of I-O

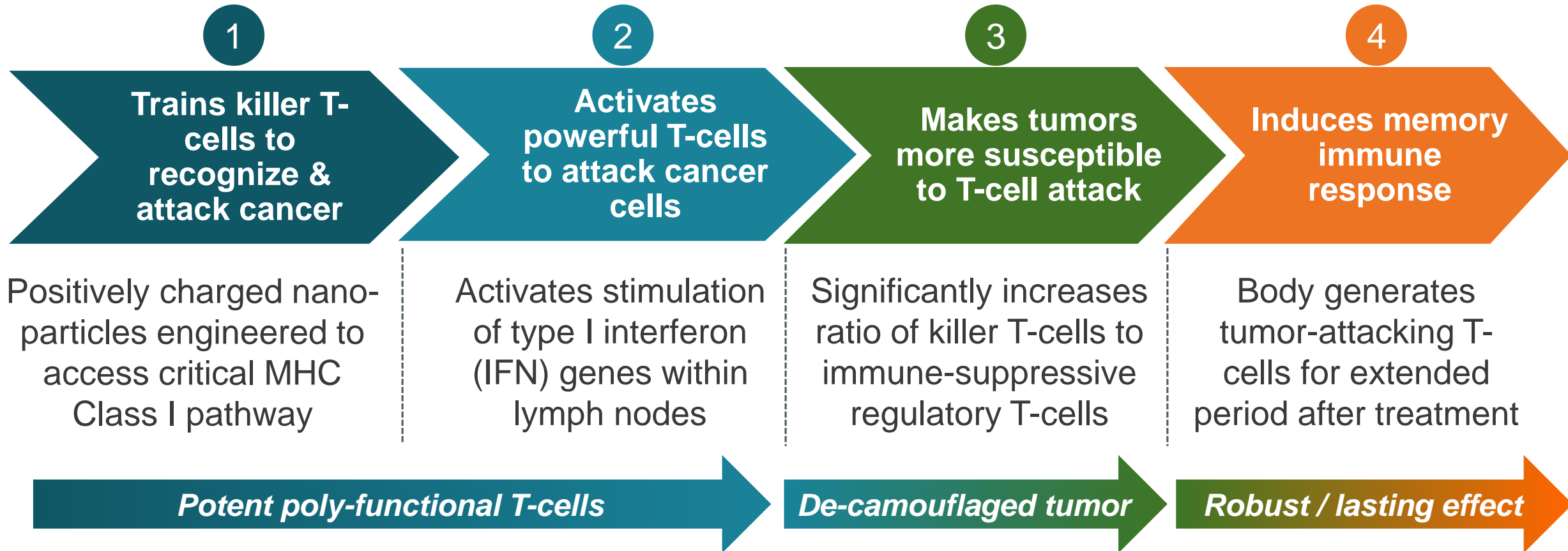
- Durability of anti-tumor responses in some patients
- Disease control for many years, resulting in improvements in duration of overall survival

## The Frustration of I-O

- Only minority of patients respond (15-25% on average)
- Additive toxicities of different I-O agents in combination, without significant corresponding clinical benefit
- **Critical unmet ability to activate the necessary immunological events/pathways to induce robust *in-vivo* T-cell response**
  - Train right phenotype of CD8+ killer T-cells
  - Activate signaling mechanisms that activate CD8+ T-cells
  - Overcome tumors' ability to evade attack by T-cells

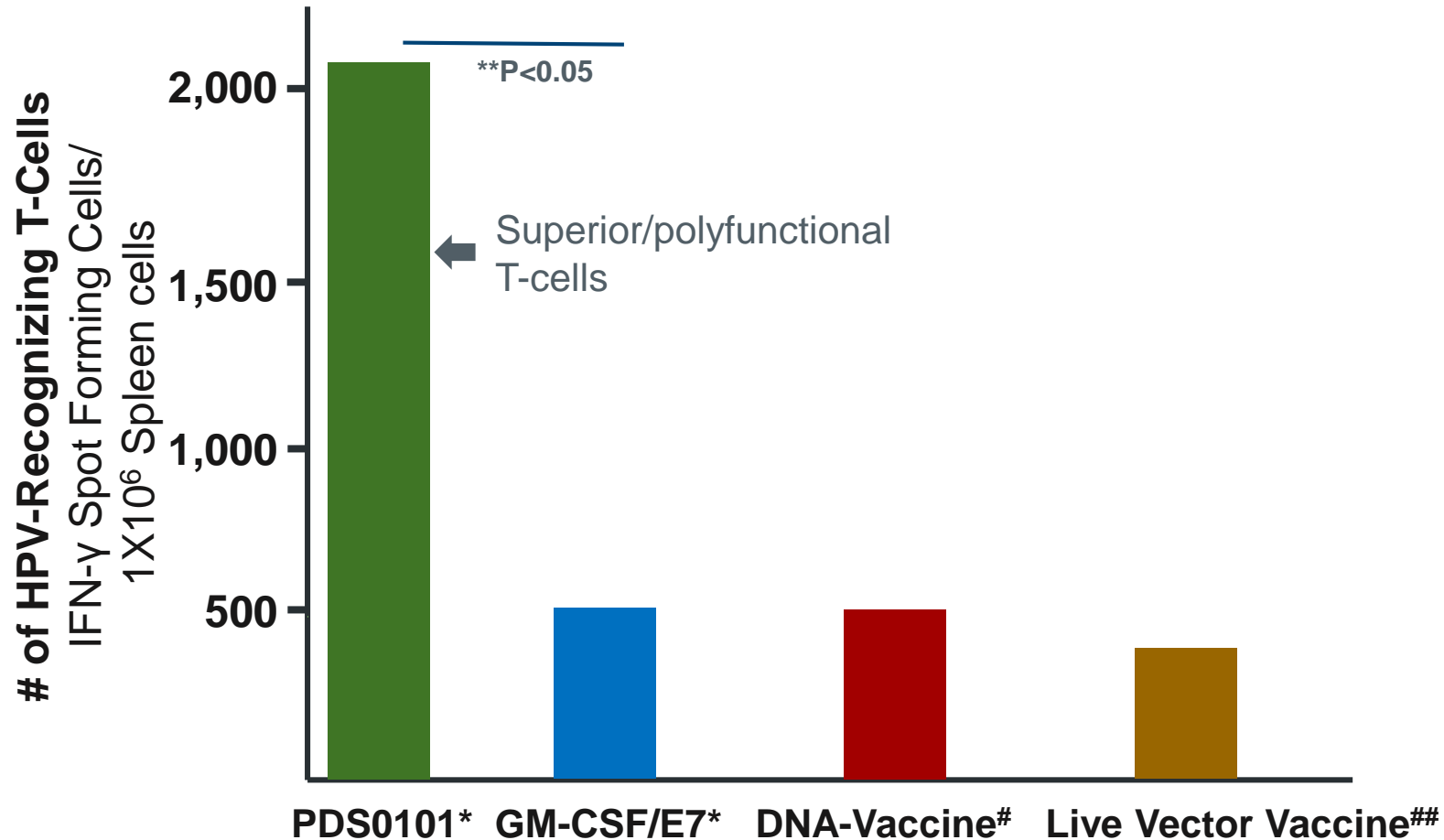
# Differentiated Versamune® Platform Overcomes Key I-O Limitations

Engineered to address the basics:  
Results in potent tumor-recognizing and attacking killer T-cells *in vivo*\*



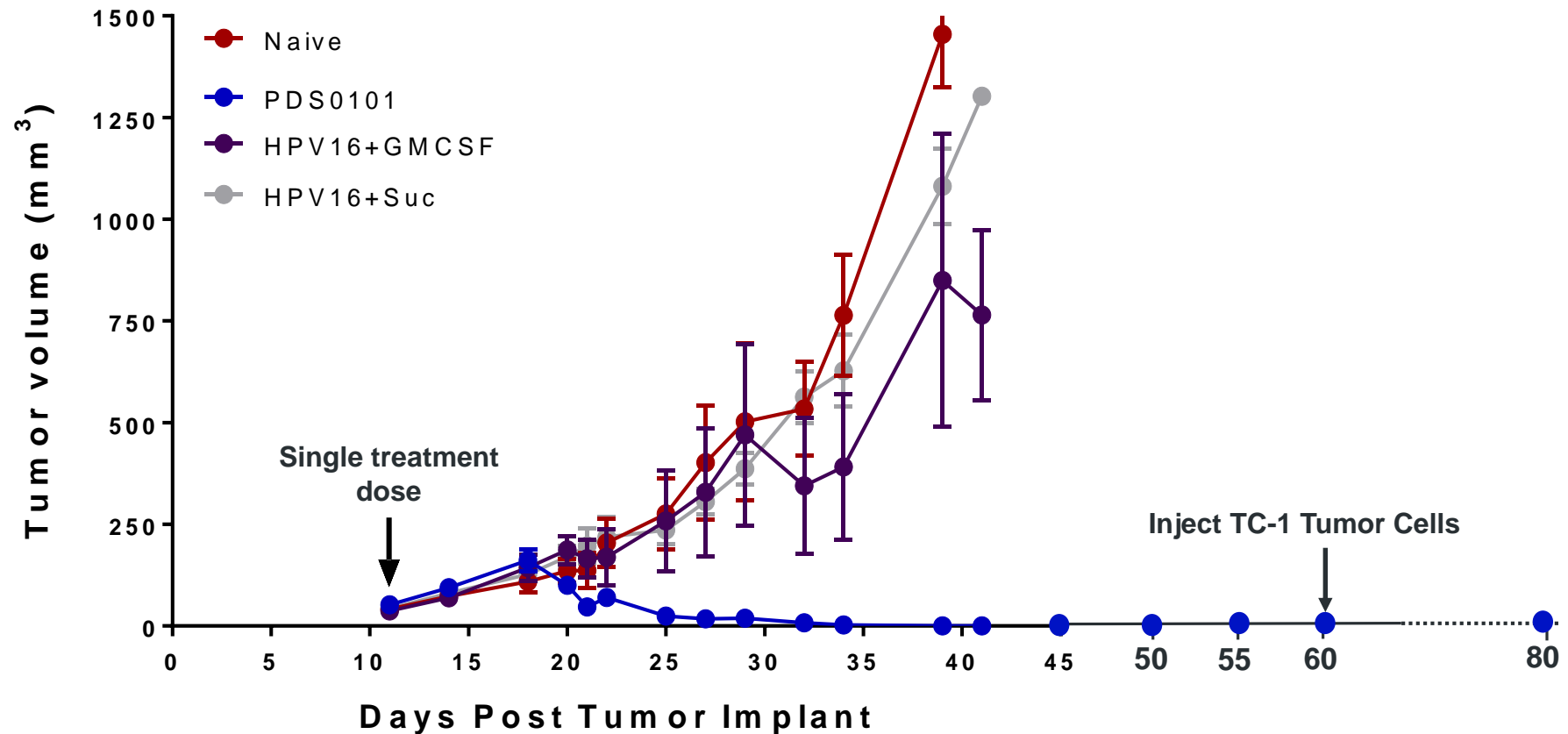
# Efficient Activation of MOAs #1 & 2: Promotes Superior Quantity & Quality of HPV-Specific Tumor-Attacking T-Cells *In-Vivo*

*Versamune<sup>®</sup> induces superior levels of CD8+ T-Cells versus competing approaches (analysis by interferon gamma ELISPOT)*

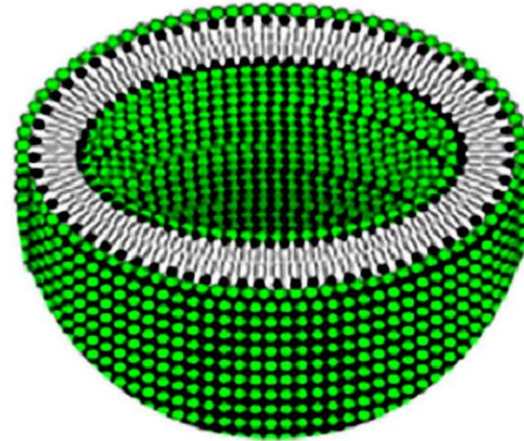
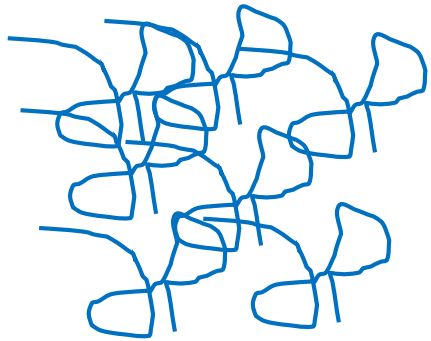


# PDS0101: Efficient Activation of MOAs #1 - 4: Promotes Unique Ability to Eliminate HPV-Positive TC-1 Tumors with Sustained T-Cell Response

*In vivo* induction of superior quantity & quality of tumor-specific CD4+ and CD8+ T-cells result in complete regression & effective T-cell memory after a single dose\*



# Unique Formulations Present Advantages in Potency, Manufacturing, and Administration



**Proprietary Antigen  
Design**

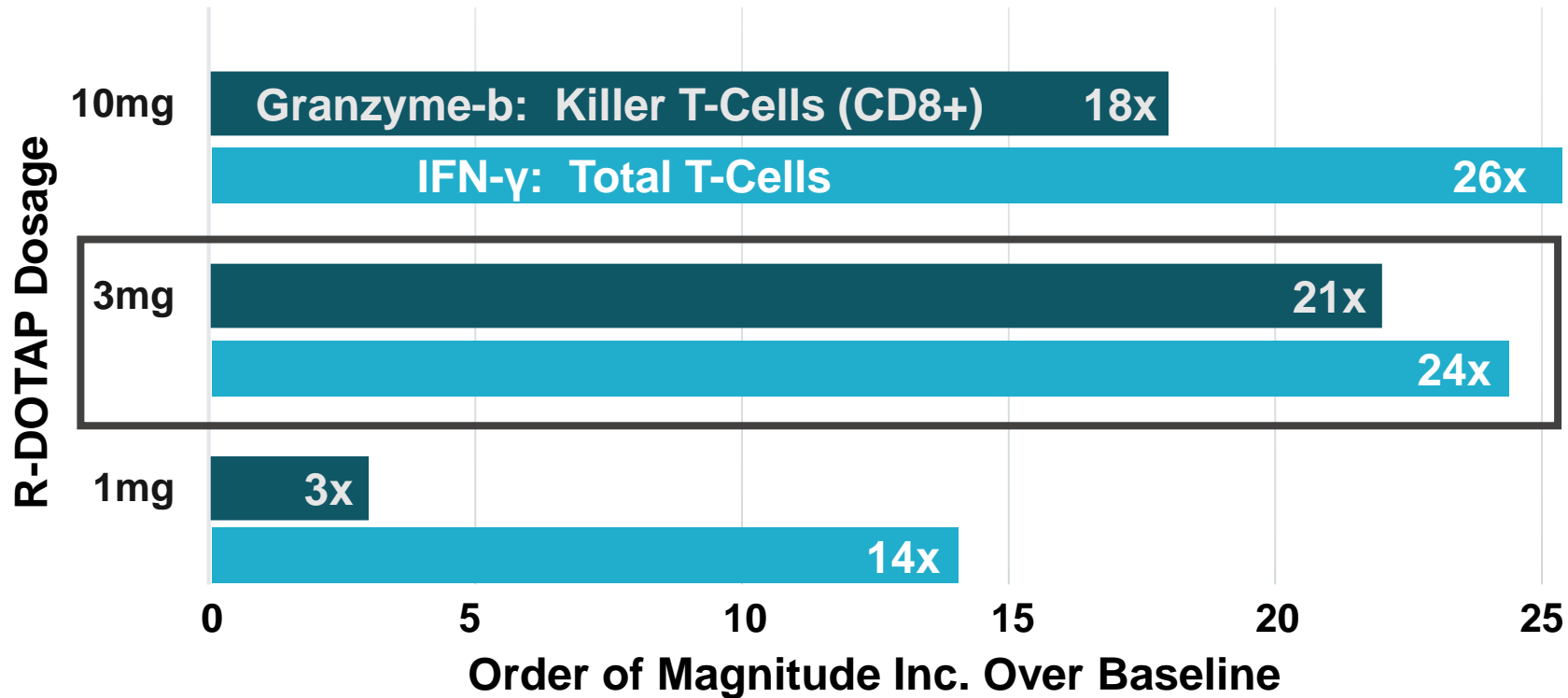
**Versamune<sup>®</sup>**

**Potential best-in-class simplicity, ease of administration and cost of goods**



# Power of PDS0101 Demonstrated in Humans: Phase 1 Dose Escalating Study Showed Potent CD8+ T-Cell Induction

>20-Fold Increase in HPV-Specific CD8+ T-Cell Responses  
Vs. Pre-Treatment Levels at Recommended Clinical Doses



## Clinical Study Design

- 12 patient open-label study (3 cohorts, each 3-6 subjects)
- Cervical Intraepithelial Neoplasia (CIN) & high-risk HPV
- Evaluated safety, tolerability & pharmacodynamics

- Strong & Measurable *In-Vivo* Induction of HPV-Specific Killer T-cells 14 Days Post Treatment
- Defined Dose for Phase 2 and Registration Studies

# PDS0101 Phase 1 Follow-up Data: Demonstrated Clinical Response in 60% of Evaluable Patients

- PDS0101 was immunologically active at all three doses resulting in 5 to 73-fold increase in circulating HPV disease-attacking T-cells in 10/12 subjects
- Clinical responses were observed in 60% of evaluable patients across the three tested doses
- Responses seen as early as 1-3 months after treatment in some patients, suggests potential correlation of immunologic and clinical responses with the administration of PDS0101

Dose Cohort	Evaluable Patients*	Clinical Response 12 Months Post Treatment**	
	N =	N =	% of Evaluable
1mg	3 of 3	2	67%
3mg	2 of 3	1	50%
10mg	5 of 6	3	60%
<b>Total</b>	10	6	60%

\*Two of twelve patients were not evaluable: one patient, who demonstrated a strong immune response, was lost to follow up and another received LEEP excision therapy (standard of care)

\*\*Two of ten evaluable patients who had clearance of CIN by cytology were not considered as clinical responders: one patient regressed from CIN to atypical squamous cells of undetermined significance (ASCUS) with detectable virus, and the other showed consistent disease elimination by cytology, but showed residual disease by colposcopy

# PDS0101 Monotherapy: Phase 2b Clinical Study in CIN2/3

## Treatment of HPV16-Positive Cervical Intraepithelial Neoplasia (CIN2/3)

(Study Initiation in 1Q 2020)

Placebo Controlled, Double Blind Study	PDS0101	PLACEBO	TOTAL
Study Sample Size	N = 100	N = 50	N = 150
Planned # of Study Sites			Up to 35
<b>Planned Interim Analysis: After ~35% of patients complete Week 32 for sample size confirmation <u>only</u></b>			

### Primary Efficacy Endpoint

- Number of subjects with regression of CIN2/3 to CIN1/normal or clearance of HPV16 DNA at Week 32 (8 months following first dose of PDS0101 in subjects receiving PDS0101 vs. placebo.

# PDS0101 + KEYTRUDA® Clinical Study in HPV-Associated Head and Neck Cancer

## First Line Treatment of HPV16 Positive Recurrent/Metastatic Head and Neck Cancer

(Study Initiation in 1Q 2020)

Open Label, Single Arm, Non-Randomized Study	TOTAL
Study Sample Size	N = 96
Anticipated # of Study Sites	~20

### Primary Efficacy Endpoint

- Objective Response Rate (ORR) at 9 months following the initial dose of combination treatment.

### Note

- Merck received FDA approval for KEYTRUDA® (checkpoint inhibitor) alone or with chemotherapy on 06/10/2019 in the first line treatment of recurrent/metastatic HNC with tumor PD-L1 expression

# PDS0101 Clinical Combination Study in Advanced HPV-Associated Cancers

## Treatment of Advanced HPV-Associated Cancers (PDS-NCI Collaboration)

(Study Initiation in 1Q 2020)

Open Label, Single Arm, Non-Randomized Study	TOTAL
Study Sample Size	N = 30
Anticipated # of Study Sites	1 (NCI Bethesda, MD)

**Combination with two novel clinical stage immunotherapies**





### Primary Efficacy Endpoint

- Percentage of subjects that achieve an objective confirmed complete or partial response using RECIST 1.1.

### Regulatory Strategy

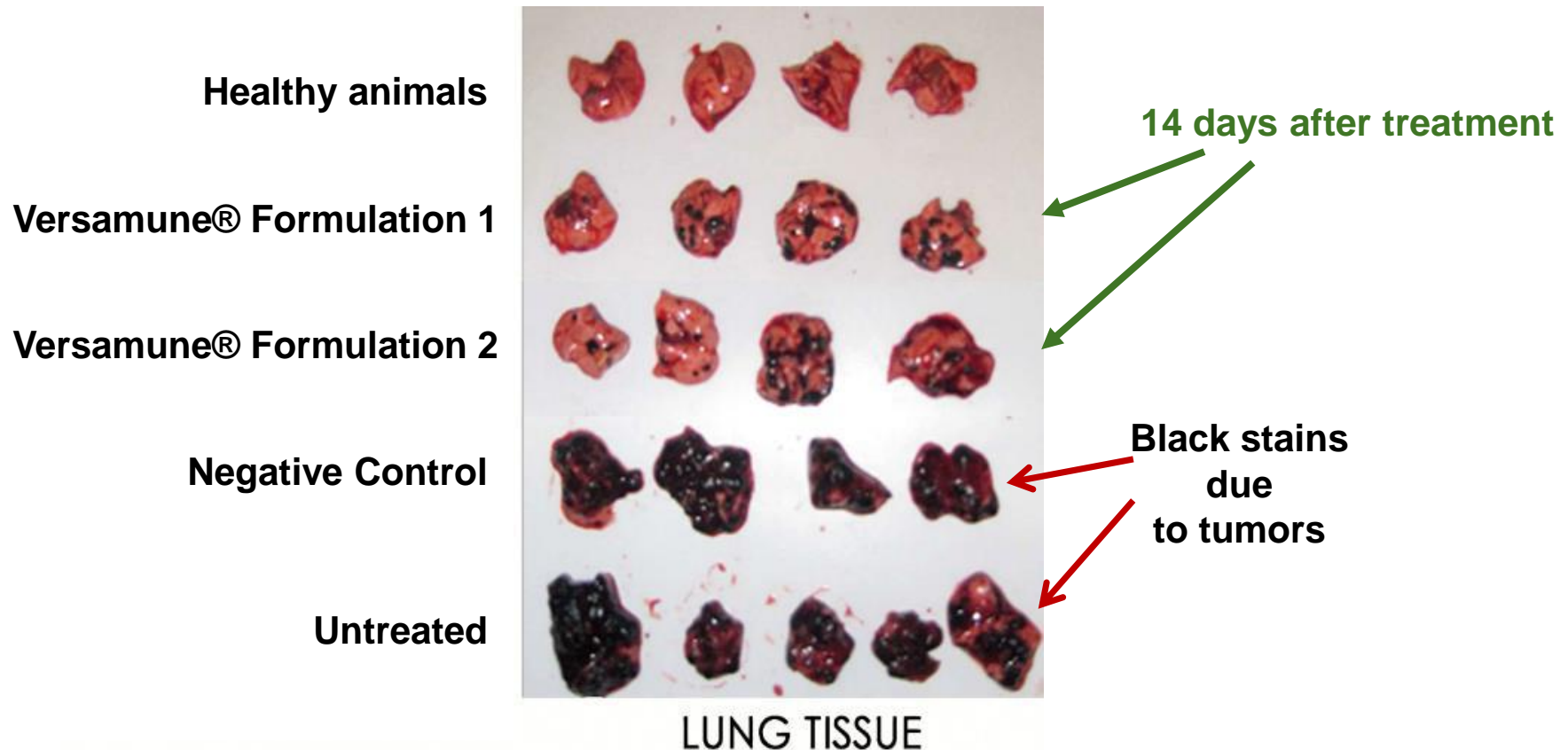
- Phase 2 trial in HPV-positive all-comers.

# Developing Broad Product Pipeline with Leaders in I-O

Product	Indication	Partner	Combination	Status
PDS0101 (HPV)	Cervical pre-cancer CIN 2/3		Monotherapy	Initiate Phase 2 1Q 2020*
	Head & neck cancer First line treatment Recurrent/metastatic	 MERCK	KEYTRUDA®	Initiate Phase 2 1Q 2020*
	Advanced HPV cancers		Novel Immunotherapies	Initiate Phase 2 1Q 2020*
	Cervical cancer Stage IIb-IVa		Chemo/Radiation Therapy	Phase 2 ready
	Anal pre-cancer AIN 2/3		Monotherapy	Phase 2 ready
PDS0102 (TARP)	Prostate and breast cancers		Immunotherapy	Preclinical
PDS0103 (MUC-1)	Ovarian, colorectal, lung, breast cancers		Immunotherapy	Preclinical
PDS0104 (Melanoma)	Melanoma		Immunotherapy	Preclinical

# PDS0104: Powerful *In-Vivo* Killer T-Cell Induction Results in Unique Ability to Regress B16 Melanoma Lung Metastasis Tumors (Preclinical)

*In vivo* induction of superior quantity and quality of tumor-specific CD4+ and CD8+ T-cells results in regression of metastatic tumors in lungs after a single dose



# Intellectual Property (Versamune<sup>®</sup> -Related Products)

## IP strategy intended to provide multiple layers of technology & product protection

- Versamune<sup>®</sup> and associated patents **100% owned by PDS**
- **Five issued US patents** valid from 2025 – 2034
- **Five issued international patent families** (including Europe & Japan)
- **10 total patent families** – provides possible protection of products through 2038
- Patents cover compositions/formulations and methods of use



# Projected Near-Term Milestones / Catalysts

- 3Q 2019: Release available patient outcome data from Phase 1 clinical study
- 1Q 2020: Initiation of CIN2/3 monotherapy Phase 2 study
- 1Q 2020: Initiation of PDS-Merck Phase 2 combination study in head and neck cancer
- 1Q 2020: Initiation of PDS-NCI Phase 2 combination study in advanced HPV-cancers
- 2Q 2020: Publication of PDS0101 Phase 1 clinical study results in peer reviewed journal

# Financial Information

## Nasdaq:

## PDSB

**Shares Outstanding<sup>1</sup>**

5.2M

**Cash<sup>1</sup>**

\$21.7M

**Share Price<sup>2</sup>**

\$5.05

**Market Cap<sup>2</sup>**

\$26.3M

**Debt<sup>1</sup>**

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# Wrap-Up

- 1** **Powerful and safe** T-cell-activating immunotherapy platform
- 2** **Versatility:** Potential to **transform** treatment of early- & late-stage cancers
- 3** **Validation:** Superior preclinical and clinical data  
Clinical partnerships with both Big Pharma and NCI
- 4** Upcoming **Phase 2 clinical studies**  
Both in monotherapy & combinations with checkpoint inhibitors

# Management Team

## Frank Bedu-Addo, PhD Chief Executive Officer



- Strategy & managed execution at both large pharma & biotechs
- Notable drug development:  
Abelcet® (Liposome Company/ Elan)  
PEG-Intron® (Schering-Plough/ Merck)

## Andrew Saik Chief Financial Officer



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

## Lauren V. Wood, MD Chief Medical Officer



- >30 years of translational clinical research experience
- Former Clinical Director of the Vaccine Branch within the Center for Cancer Research, National Cancer Institute

## Gregory Conn, PhD Chief Science Officer



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



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