# INVESTOR PRESENTATION

NASDAQ: PDSB | March 2022

# PDS Biotechnology

#### Precision Designed Science For Immunotherapy



## **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 ("SEC") 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.

#### **Company Overview**

Clinical-stage Company developing molecularly targeted immunotherapies to treat cancer and infectious disease

2

Versamune<sup>®</sup> and Infectimune<sup>™</sup> platforms leverage the body's own defense systems to induce disease-specific killer T-cells and antibodies to combat cancer and infectious disease

3

The initial concept for Versamune<sup>®</sup> and Infectimune<sup>™</sup> was developed by Prof. Leaf Huang PH.D., a world renowned pioneer in nanoparticle drug delivery



Four Phase 2 oncology clinical trials with multiple readouts anticipated in Q2/Q3

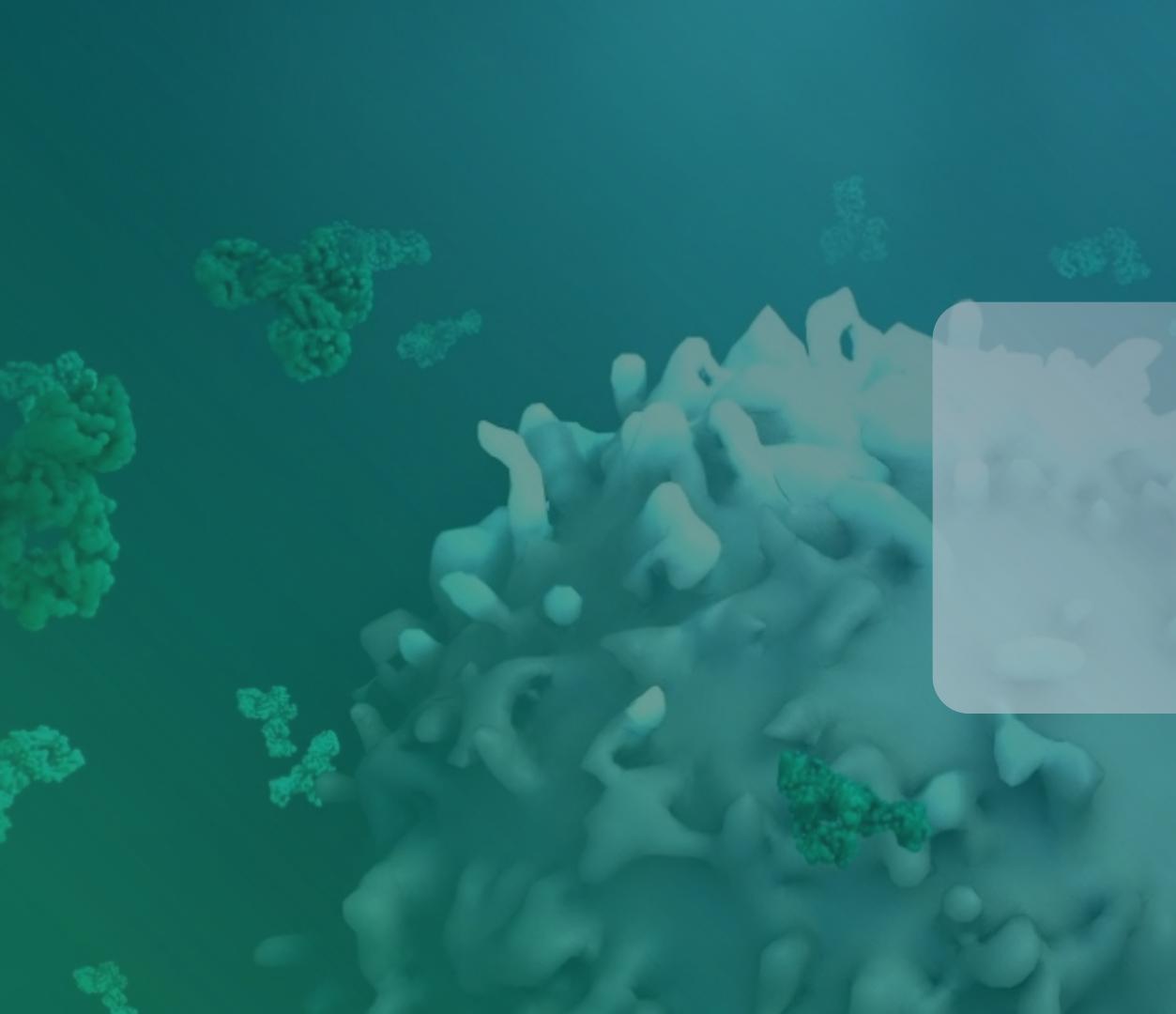


Clinical partnerships with Merck, MD Anderson Cancer Center, National Cancer Institute and Mayo Clinic

6

Debt free with approximately **\$65.2M** in cash (unaudited) as of December 31, 2021





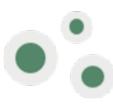
# Versamune® Oncology Platform



## **The PDS Biotech Differentiation**

Versamune<sup>®</sup> is designed to promote powerful, CD8+ killer T-cell responses *in vivo* 

Versamune<sup>®</sup>-based therapies also show promising potential to:



Generate the right type and quantity of effective CD8+ killer T-cells



Generate memory T-cells, to enhance durability of response



Generate potency without serious systemic side effects

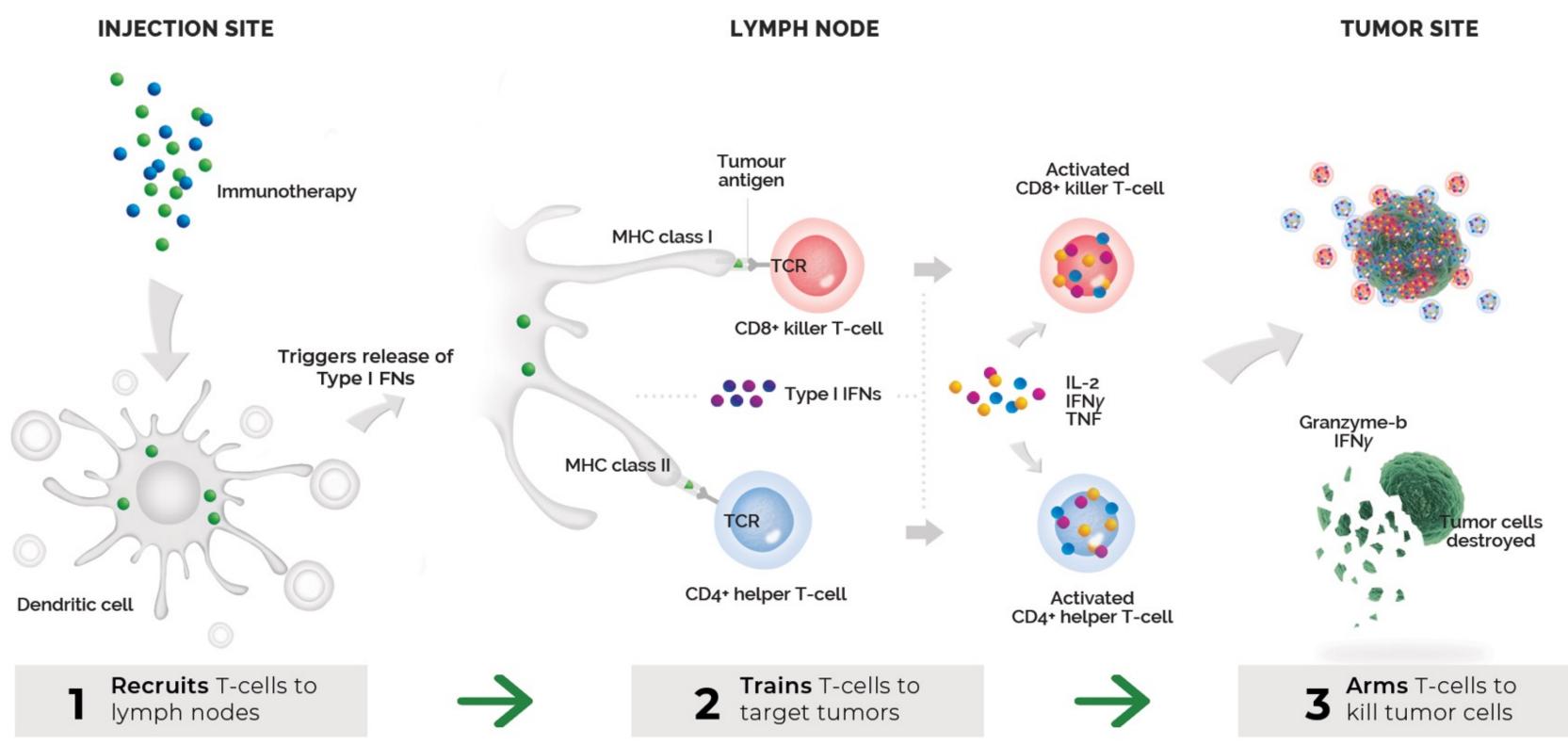


# 15-30%

Success in checkpoint inhibitor treatments due to low CD8+ T-cell response\*

#### Versamune<sup>®</sup> Platform

Designed to Recruit, Train and Arm T-cells in the Body



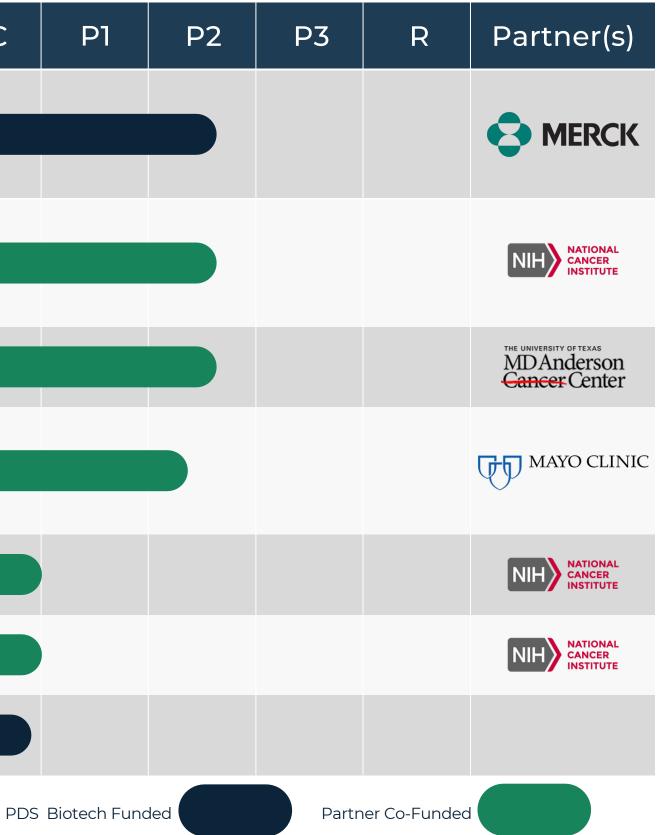
References: Gandhapudi SK, et al. 2019. Antigen priming with enantiospecific cationic lipid nanoparticles induces potent antitumor CTL responses through novel induction of a Type I IFN response. J Immunol. 202 (12): 3524-3536. Smalley R umfield C et al. 2020. Immunomodulation to enhance the efficacy of an HPV therapeutic vaccine. J. for ImmunoTherapy of Cancer 8:e000612.

#### Versamune<sup>®</sup> Platform

Versamune<sup>®</sup>-based oncology pipeline is being developed in partnership with the leaders in immuno oncology

Candidate	Indication	Combination	PC
PDS0101 (HPV16) <i>VERSATILE-002</i>	Recurrent/metastatic HPV16-positive head and neck cancer <u>Arm 1</u> : CPI naïve 1st line treatment <u>Arm 2</u> : CPI refractory 2nd or 3rd line treatment	KEYTRUDA (standard of care)	
PDS0101 (HPV16) <i>NCI-led Triple</i> <i>Combination</i>	HPV-positive anal, cervical, head and neck, penile, vaginal, vulvar cancers <u>Arm 1</u> : CPI naive 2nd line treatment <u>Arm 2</u> : CPI refractory 3rd line treatment	Bintrafusp and M9241	
PDS0101 (HPV16) <i>IMMUNOCERV</i>	1st line treatment of locally advanced (IB3- IVA) cervical cancer	Chemo-radiation (standard of care)	
PDS0101 (HPV16) Mayo Clinic	Pre-metastatic HPV-associated oropharyngeal cancer (OPSCC) <u>Arm 1</u> : PDS0101 monotherapy <u>Arm 2</u> : PDS0101 + KEYTRUDA	KEYTRUDA (standard of care)	
PDS0102 (TARP)	TARP-associated AML, prostate and breast cancers	TBD	
PDS0103 (MUC1)	MUC-1 associated breast, colon, lung, ovarian and other cancers	TBD	
PDS0104 (TRP2)	Melanoma	TBD	





#### PDS0101: Lead Asset

Designed to treat human papillomavirus (HPV16)-associated cancers

#### \$6B Market Opportunity<sup>1</sup>

More than <u>46,000<sup>2</sup></u> patients were estimated to have been diagnosed last year with HPV-associated cancers in the US<sup>1,2</sup>

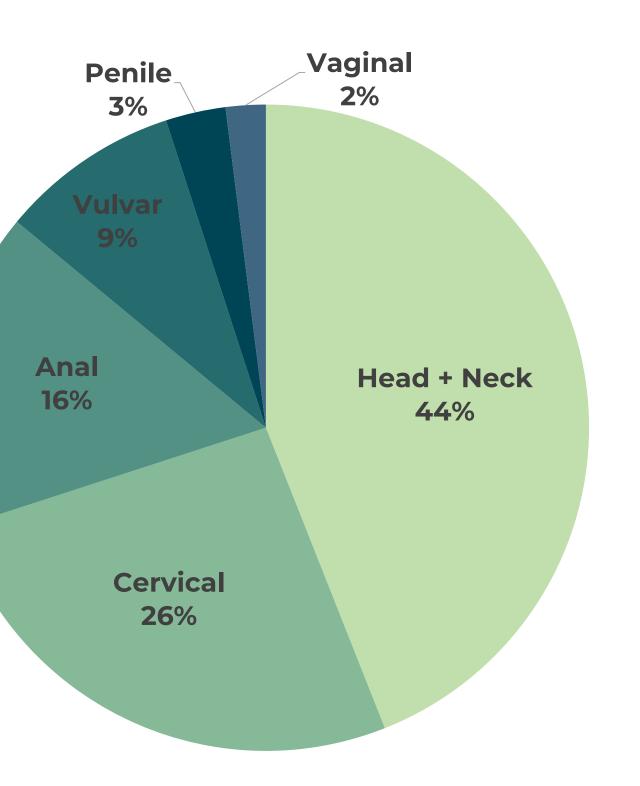
HPV vaccination is <u>not</u> expected to impact the rate of HPVrelated cancer incidence for decades

Existing immunotherapies cost <u>\$150,000+</u> annually per patient<sup>1</sup>

<sup>1</sup>Company estimates based on CDC data. Assessments have not been adjusted to reflect HPV16-expression <sup>2</sup>CDC website



#### US HPV-associated cancer incidence<sup>2</sup>



## **Phase 2: PDS0101 + M9241 + Bintrafusp alfa** Investigator-led trial evaluating the combination in patients with advanced refractory HPV-associated

Indication	Treatment of patients with HPV16-associated cancer who ha
<b>Clinical Agents</b>	<u>Bintrafusp alfa</u> : Bifunctional fusion protein targeting TGF-β <u>M9241 (NHS-IL12)</u> : Antibody-conjugated immunocytokine <u>PDS0101</u> : Versamune <sup>®</sup> -based immunotherapy generating H
Study Goals	<u>Group 1</u> : Objective response rate (ORR) as second-line treatr <u>Group 2</u> : ORR as third-line treatment in patients who have f
Achieved	Preliminary efficacy & safety data presented at ASCO 2021
Timing	Detailed, updated efficacy data to be presented at a confere
Trial Partner	

# Confirmation that PDS0101 enhances the therapeutic benefit of checkpoint inhibitors could expand evaluation of Versamune®-based therapies in multiple cancer indications

cancers

have failed prior treatment

and PD-L1

HPV-specific CD8+ and CD4+ T-cells

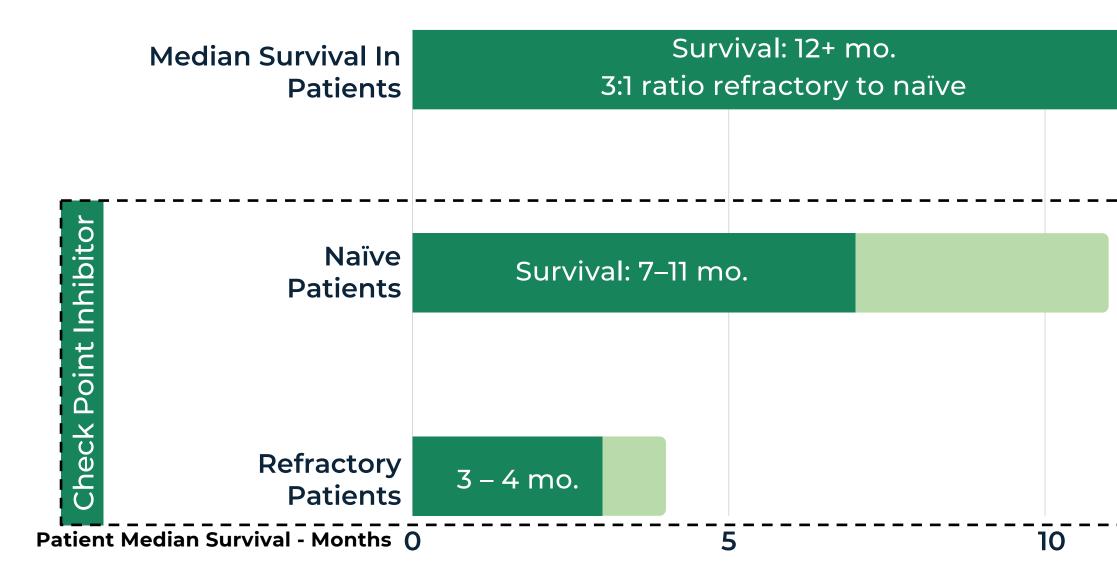
tment in checkpoint inhibitor (CPI) naïve patients failed CPI therapy (CPI refractory)

rence in 2022

## **PDS0101: Triple Combination**

Promising survival of patients with advanced refractory HPV16-associated cancers

#### PDS0101 + Bintrafusp alfa + M9241 Indications targeted in study-cervical, anal, head and neck, vaginal, penile



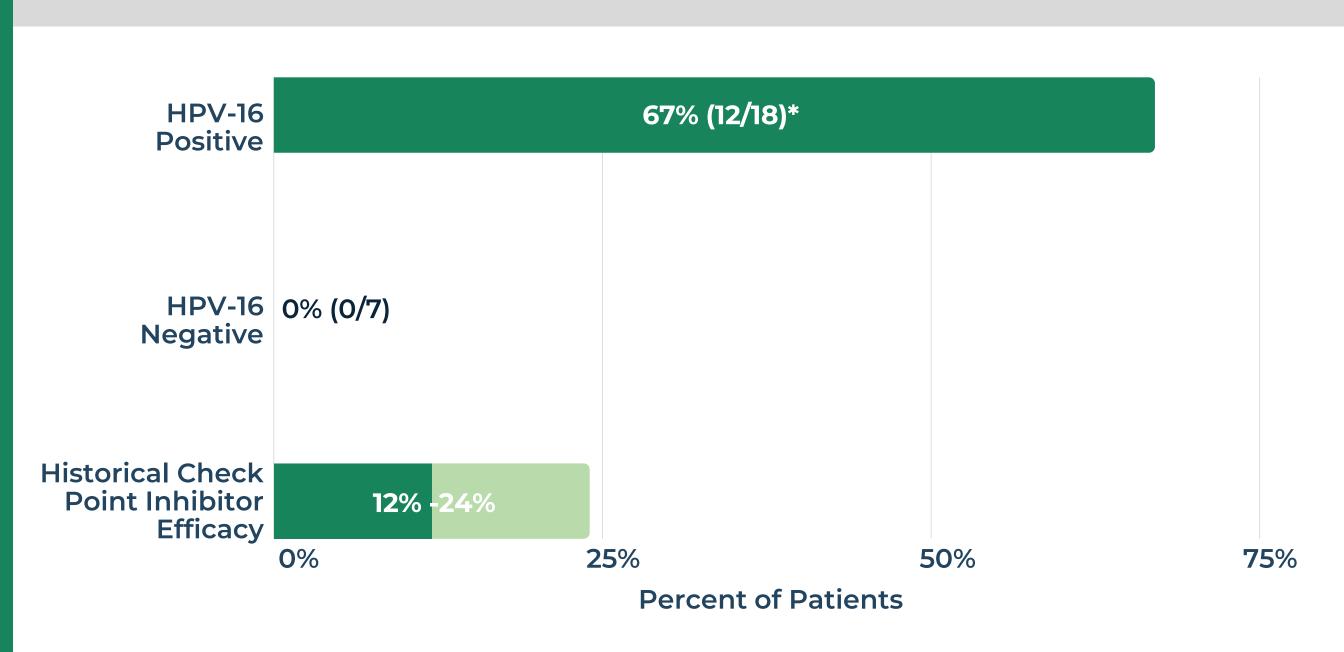


- 37 patients (30 HPV16 positive) evaluated
- Study progressing and recruiting; updates will be provided in the future

#### Triple Combo: PDS0101 + bintrafusp alfa + M9241 Advanced cancer patients with tumor shrinkage who had failed prior therapy

### **PDS0101**: **Triple Combo**

Versamune<sup>®</sup> induced HPV-16 CD8+ killer T-cells



\*These numbers reflect data as of evaluation of 25 patients; numbers will change as more patients undergo evaluation, includes both CPI refractory and naïve patients.

Reference: Strauss J. et al. Phase II evaluation of the triple combination of PDS0101, M9241, and Bintrafusp alfa in patients with HPV 16 positive malignancies. Presented at: American Society of Clinical Oncology 2021 Annual Meeting; June 4-8, 2021; Virtual. Abstract: 2501.



#### Phase 2: PDS0101 + KEYTRUDA<sup>®</sup>

Company-sponsored trial for the treatment of HPV16-positive metastatic/recurrent head and neck cancer (VERSATILE-002)

Trial Partner	
Timing	Detailed preliminary efficacy data to be presented at a conf
Achieved	Safety data presented at Head and Neck Symposium Q1 202 Preliminary efficacy data released; achieved initial efficacy r
Study Goals	<u>Group 1</u> : Objective response rate (ORR) as first-line treatmer <u>Group 2</u> : ORR in patients who have failed checkpoint inhibit
<b>Clinical Agents</b>	<u>KEYTRUDA®(Standard of Care)</u> : Anti-PD1 checkpoint inhibite <u>PDS0101</u> : Versamune®-based immunotherapy generating H
Indication	Treatment of patients with HPV16-positive head and neck c

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

cancer whose cancer has spread or returned

tor (ORR ~20%) HPV-specific CD8+ and CD4+ T-cells

ent in checkpoint inhibitor (CPI) naïve patients itor therapy (CPI refractory)

)22

milestone Q1 2022 in Group 1

ference in 2022

#### Phase 2: PDS0101 + Chemoradiotherapy

Investigator-led trial evaluating the combination in patients with locally advanced cervical cancer (IMMUNOCERV)

Indication	Treatment of patients with locally advanced cervical cancer
<b>Clinical Agents</b>	<u>Chemoradiotherapy (CRT –Standard of Care)</u> : Cisplatin and I <u>PDS0101</u> : Versamune <sup>®</sup> -based immunotherapy generating HI
Study Goals	Safety, rate of regression and local control in patients with p
Timing	Preliminary data anticipated late Q2/early Q3 2022
Trial Partner	THE UNIVERSITY OF TEXAS MDAnderson Cancer 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

er-Stages IB3-IVA

radiation therapy HPV-specific CD8+ and CD4+ T-cells

primary tumor ≥5cm (n=35 patients)

#### **Phase 2: PDS0101 Monotherapy and in Comb. with KEYTRUDA**<sup>®</sup> Investigator-led trial evaluating treatments in patients with HPV-associated oropharyngeal cancer with

Investigator-led trial evaluating treatments in patients with HPV-a high risk of recurrence

Indication	Treatment of patients with oropharyngeal cancer prior to tr
<b>Clinical Agents</b>	<u>KEYTRUDA®</u> : Cisplatin and radiation therapy <u>PDS0101</u> : Versamune®-based immunotherapy generating H
Study Goals	Safety, rate of regression and local control in patients transo
Timing	Approved by the IRB and anticipate enrollment will begin in
Trial Partner	MAYO CLINIC

#### If successful, this study could support the expansion of PDS0101 to earlier stage disease

ransoral robotic surgery

HPV-specific CD8+ and CD4+ T-cells

soral robotic surgery

in Q1

## **PDS0102: TARP** Antigen

Versamune<sup>®</sup>-induced CD8+ killer T-cells may result in the ability to treat TARP positive AML and prostate cancers



#### Announced license with NCI TARP antigens

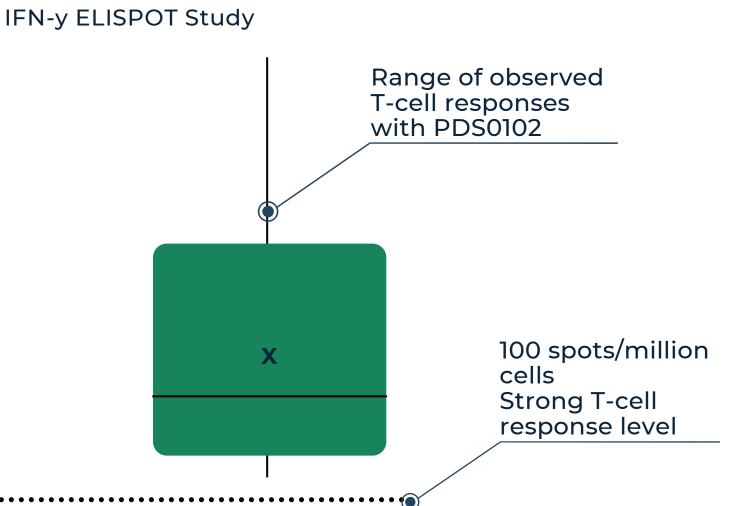
1000 900 800 Number of TARP-Specific T-cells (Interfer on-y spot forming cells per million splenocytes) 700 600 500 400 300 200 100 0 **CFA + TARP (1-20)** 

1 Reference: Wood LV et al, Oncoimmunology, 2016, Vol. 5 (8) CFA –Complete Freund's Adjuvant a highly potent immune activator not used in humans due to potentially lethal toxicity

\*Reference: Surveillance Research Program, National Cancer Institute SEER Assumes \$150K for annual course of therapy; in line with current immunotherapy treatment. Assessments have not been adjusted to reflect TARP expression, which is currently unknown by tumor type



#### **Pre-Clinical Optimization Studies**<sup>1</sup>: TARP-Specific T-cell Induction after 2 injections of PDS0102



#### Versamune<sup>®</sup> + TARP (1-20)

## **PDS0103: MUC1** Antigen

Greater quantity and quality of Versamune<sup>®</sup>-induced CD8+ killer T-cells may result in the ability to treat breast, ovarian, lung, and colon cancers

**\$100B** MUC1 Total Market Opportunity\*

Induced a >10-fold number of polyfunctional (highly potent) MUC1 specific CD8+ T-cells

# of Antigen-Recognizing CD8+ T- Cells IFN-ySpot Forming Cells/1X106Spleen Cells

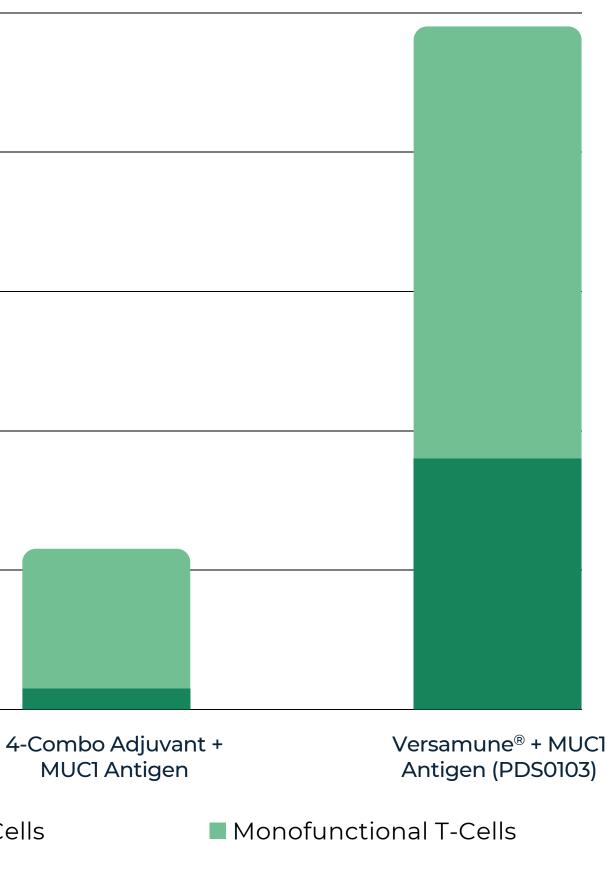


Polyfunctional T-Cells

\*References: Surveillance Research Program, National Cancer Institute SEER, Cancer Institute SEER, Assumes \$150K for annual course of therapy; in line with current immunotherapy treatment, Assessments have not been adjusted to reflect MUC1-expression, which is currently unknown by tumor type Adjuvant = cytokine GMCSF

April, Vol 8 Issue 334; Vaccine 2009, September 25, 27 (42):5906.

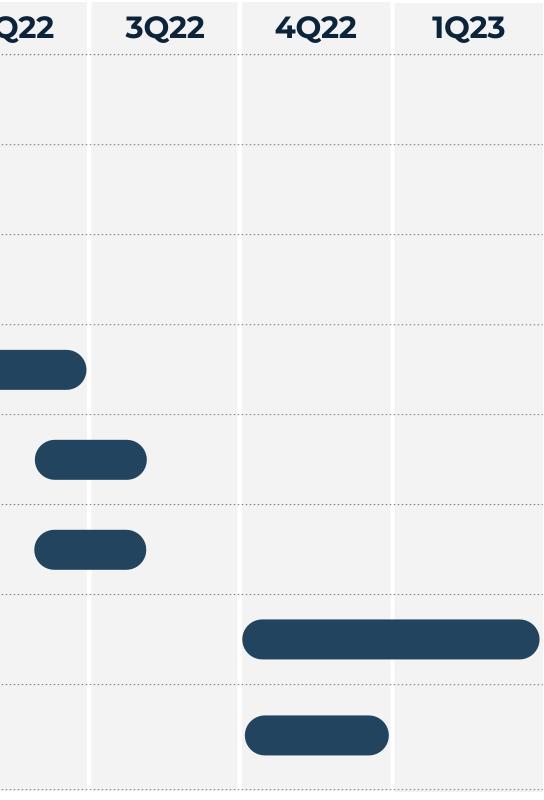


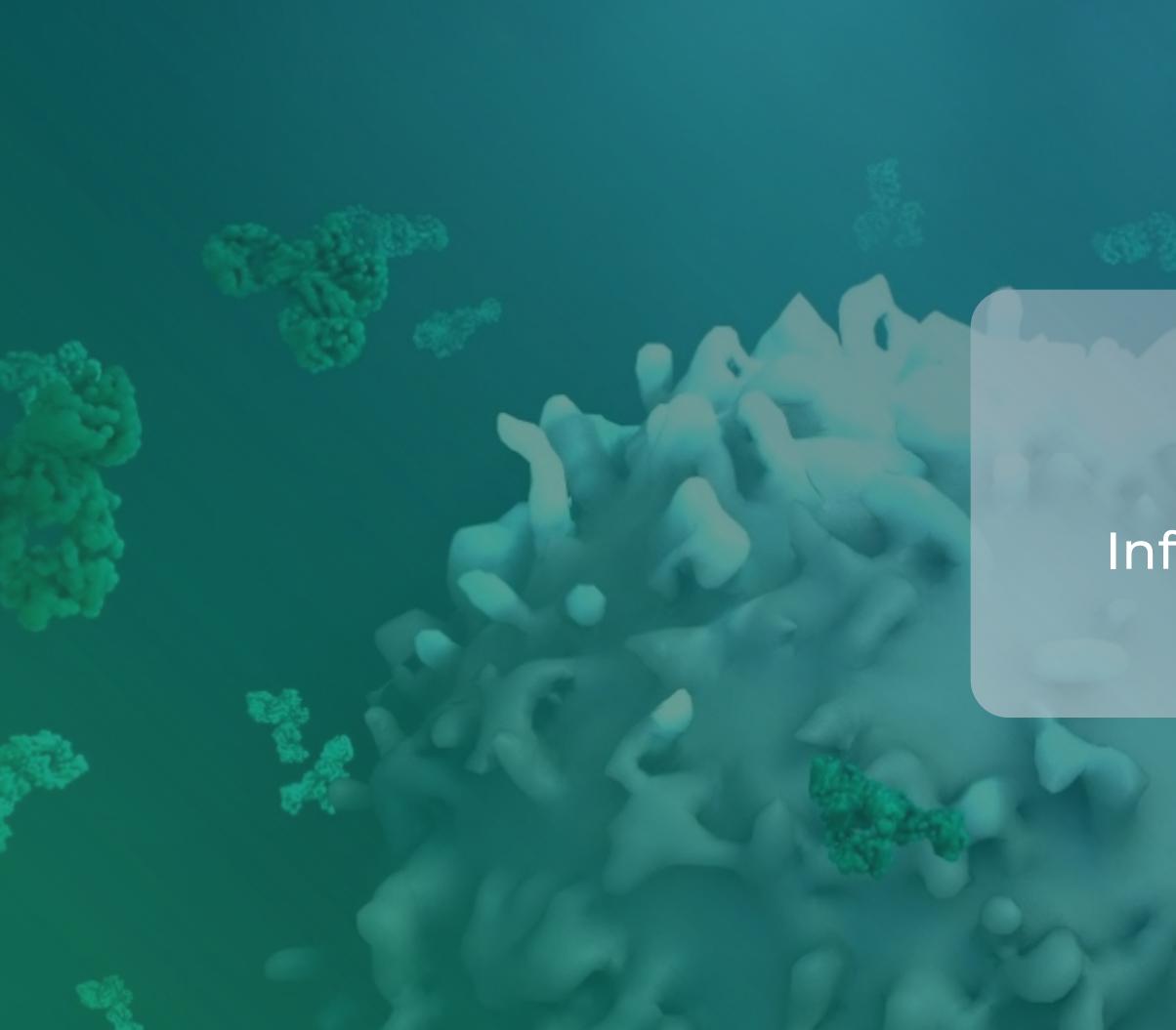


## Projected Milestones Through 1Q 2023\*

		1H21	2H21	1Q22	2Q
PDS0101	Interim data from HPV-associated cancer trial ASCO - (NCI)				
	Preliminary data from VERSATILE- 002 (KEYTRUDA® combo) (go, no go)				
	Achieved enrollment objective of HPV- associated cancer trial CPI refractory arm (NCI)				
	Anticipated updated efficacy data from NCI trial				
	Anticipated updated efficacy data from VERSATILE-002 (KEYTRUDA® combo)				
	Anticipated preliminary data from IMMUNOCERV (MD Anderson)				
	Anticipate preliminary efficacy data from Mayo Clinic IIT				
PDS0103	Estimated IND approval / Planned initiation of Phase 1/2 clinical trial in MUC1-related cancers				

9





# Infectious Disease Platform



## **PDS Biotech's Infectimune™ Pipeline**

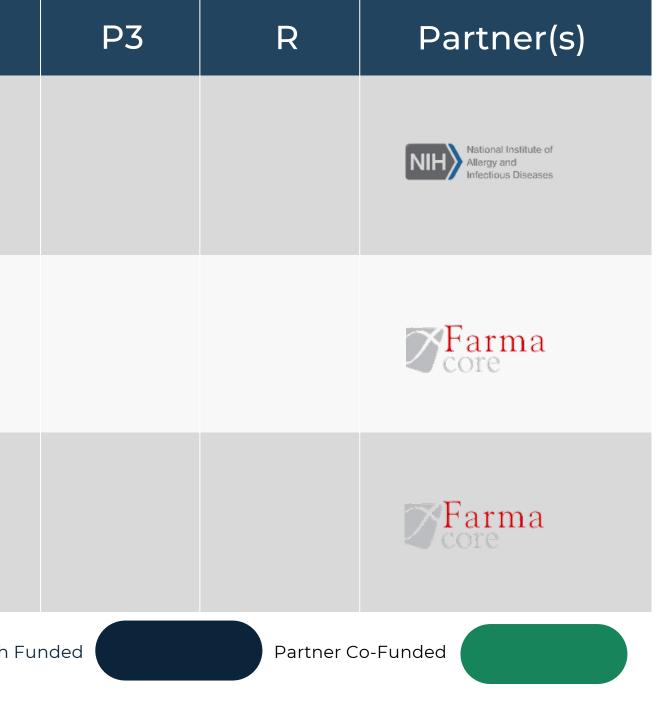
Developed in partnership with leaders in infectious disease

Candidate	Indication	PC	Pl	P2
PDS0202 (influenza)	Universal prevention of influenza			
PDS0203 (SARS-CoV-2)	Prevention of COVID-19			
PDS0201 (M-tuberculosis)	Prevention of tuberculosis			

PDS Biotech Funded

\*Consortium of PDS Biotech, Farmacore Biotechnology. Funding provided by The Ministry of Science, Technology and Innovation of Brazil ("MCTI"). Reference: Data on file.

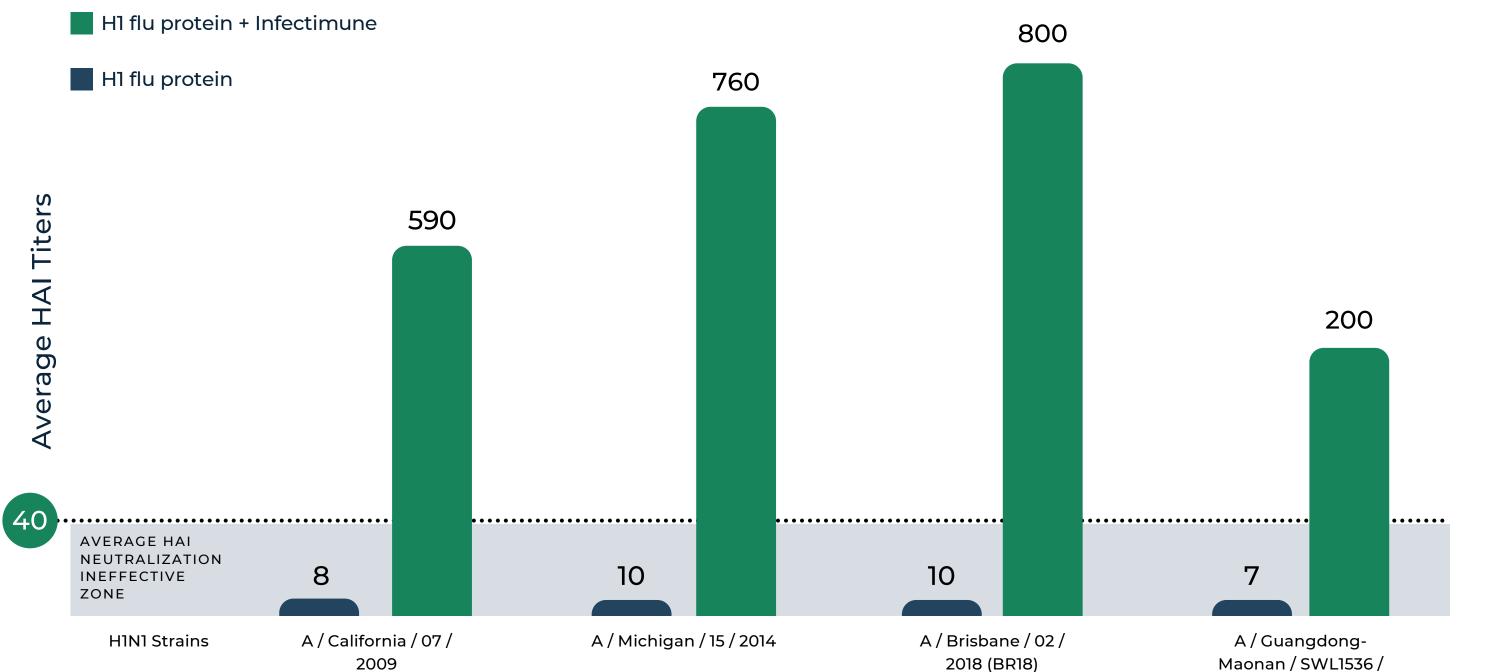




## **PDS0202: Universal Prevention of Influenza**

Provided Effective Neutralization Against Multiple Strains of Flu Viruses in Preclinical Study

Average HAI Neutralization Titer Levels Induced by PDS0202 for Various Flu Strains vs Required Levels



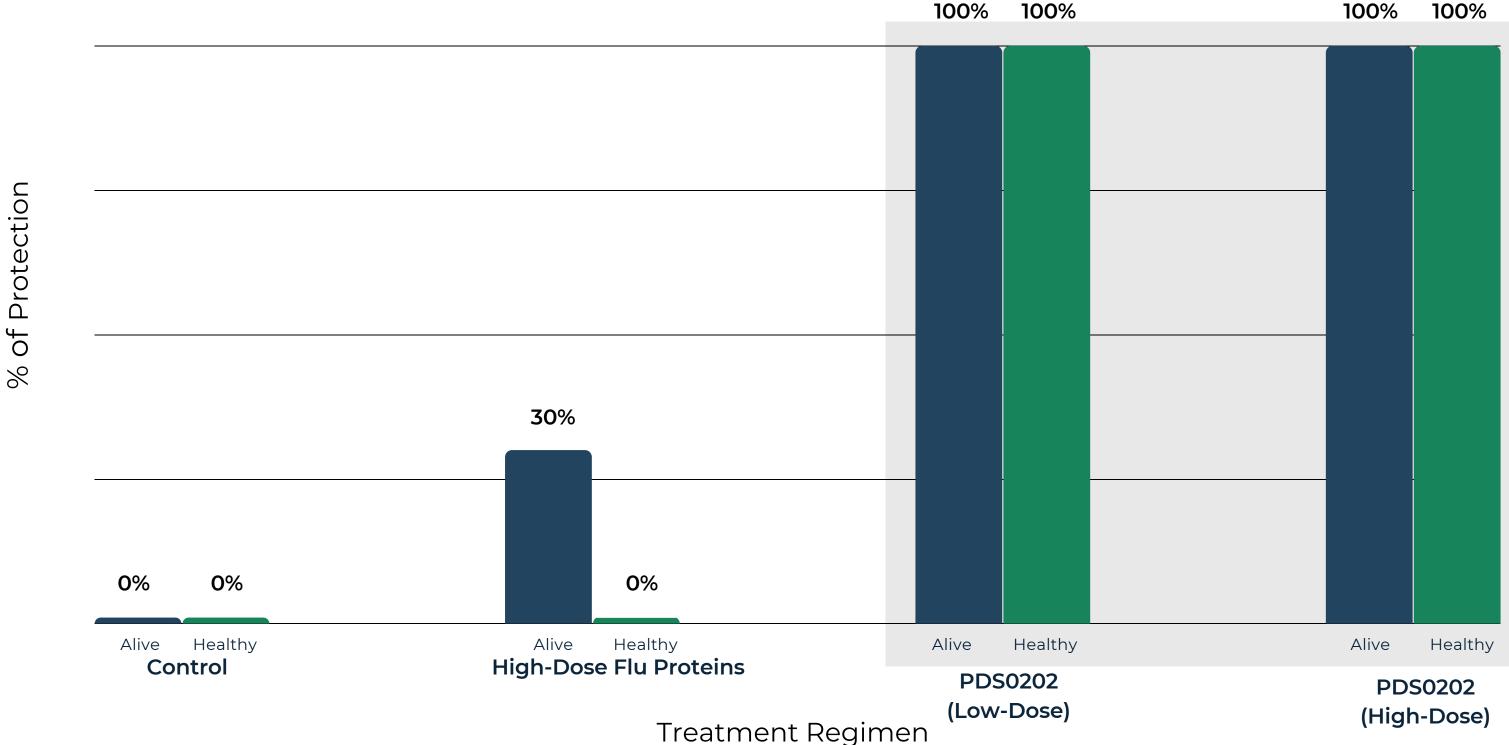


2019 (GD19)

### **PDS0202: Universal Prevention of Influenza**

Provided Protection in Preclinical Study in Keeping Subjects Alive and Healthy Against Challenge with Flu Virus

% of Protection of Subjects Challenged with the Flu Virus





Reference: Ross T. and Woodward J. et al. evaluation of the PDS0202 (Infectimune™+ COBRA) Universal flu formulation.

## Infectimune<sup>TM</sup> **Pipeline Highlights**

#### **Universal Flu**

- Announced agreement for license with University of Georgia for universal flu antigens
- Top-line preclinical data released
- Preclinical data to be submitted to peer reviewed journal for publication and future conferences

## COVID

- May 2022



• Agreement with Farmacore extended through

• Scale up and manufacturing currently in process

## **PDS Biotech Management**

Historical success in the development and commercialization of leading pharmaceutical products

<b>Frank Bedu-Addo, PHD</b> Chief Executive Officer	<ul> <li>Senior executive experience with management of strategy and execution pharma and biotechs</li> <li>Notable drug development: Abelcet<sup>®</sup> (Liposome Company/ Elan) PEG-Intron<sup>®</sup> (Schering-Plough/ Merck)</li> </ul>
<b>Matthew Hill</b> Chief Financial Officer	<ul> <li>20 years of financial and operational leadership roles for life sciences com</li> <li>Former Chief Financial Officer of several publicly traded companies</li> </ul>
<b>Lauren V. Wood, MD</b> Chief Medical Officer	<ul> <li>30 years of translational clinical research experience</li> <li>Former Director of Clinical Research at National Cancer</li> <li>Institute Center for Cancer Research (Cancer Vaccine Branch)</li> </ul>
<b>Gregory Conn, PHD</b> Chief Scientific Officer	<ul> <li>Co-founder</li> <li>35 years of drug development experience</li> <li>In-depth experience with biotech drug discovery, product development ar</li> </ul>





#### **Company Overview**

Clinical-stage Company developing molecularly targeted immunotherapies to treat cancer and infectious disease

2

Versamune<sup>®</sup> and Infectimune<sup>™</sup> platforms leverage the body's own defense systems to induce disease-specific killer T-cells and antibodies to combat cancer and infectious disease

3

The initial concept for Versamune<sup>®</sup> and Infectimune<sup>™</sup> was developed by Prof. Leaf Huang PH.D., a world renowned pioneer in nanoparticle drug delivery



Four Phase 2 oncology clinical trials with multiple readouts anticipated in Q2/Q3



Clinical partnerships with Merck, MD Anderson Cancer Center, National Cancer Institute and Mayo Clinic

6

Debt free with approximately **\$65.2M** in cash (unaudited) as of December 31, 2021



# INVESTOR PRESENTATION

NASDAQ: PDSB | March 2022

# PDS Biotechnology

#### Precision Designed Science For Immunotherapy

