



**PDS Biotechnology**  
Next Generation Immunotherapies

***A new generation of multi-functional  
cancer immunotherapies***

March 2019

# Forward-Looking Statements

This presentation contains forward-looking statements about Edge Therapeutics, Inc. (“Edge”) and PDS Biotechnology Corporation (“PDSB”), and their respective 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 by Edge 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, neither Edge nor PDS undertakes any obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

# Other Important Information

In connection with a proposed strategic merger, Edge has filed relevant materials with the Securities and Exchange Commission (SEC), including a registration statement on Form S-4 that contains a proxy statement and prospectus. Investors may obtain the proxy statement/prospectus, as well as other filings containing information about Edge, free of charge, from the SEC's Web site ([www.sec.gov](http://www.sec.gov)). In addition, investors and securityholders may obtain free copies of the documents filed with the SEC by Edge by directing a written request to: Edge Therapeutics, Inc. 300 Connell Drive #4000, Berkeley Heights, NJ 07922, Attention: Corporate Secretary or delivered via e-mail to [investors@edgetherapeutics.com](mailto:investors@edgetherapeutics.com). Investors and securityholders are urged to read the proxy statement, prospectus and the other relevant materials before making any voting or investment decision with respect to the merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

## Participants in the Solicitation

Edge and PDSB and their respective directors and executive officers and certain of their other members of management and employees may be deemed to be participants in the solicitation of proxies from the stockholders of Edge in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger is included in the proxy statement/prospectus referred to above. Additional information regarding the directors and executive officers of Edge is also included in the Edge Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 21, 2019. These documents are available free of charge from the sources indicated above.

# PDS Biotechnology Corporation (PDSB)

- PDS Biotechnology Corporation (Princeton, NJ; Private) and Edge Therapeutics, Inc. (Berkeley Heights, NJ; Nasdaq: EDGE) have agreed upon a merger, subject to Edge stockholder approval and the satisfaction of certain other conditions precedent
- The combined company will be based in NJ, and will operate as PDS Biotechnology Corporation (Nasdaq: expected symbol PDSB)
  - Merger close expected mid-late March 2019
  - Focus on developing Versamune<sup>®</sup>-based immuno-oncology products
  - PDS has operated as a private company since 2007
- Following the merger, PDSB's profile will be:
  - Clinical-stage company with upcoming potential registration & Phase 2 studies
  - 10 full-time employees based in NJ

# Investment Highlights

## PDS Biotechnology

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

## Versamune® 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 efficacy, potency, and safety
- Well-tolerated subcutaneous administration using off-the-shelf product

## Lead Asset PDS0101

- Powerful CD8+ and CD4+ T-cell responses confirmed in Phase 1/2a clinical study
- Targeting multiple indications in >\$6 billion HPV cancer market\*
- PDS0101 clinical studies projected to start Q4 2019:
  - Potential registration CIN 2/3 monotherapy study
  - Phase 2 combination with Keytruda® in first-line head and neck cancer
- Multiple additional Phase 2 monotherapy and combinations studies planned

## Funding

- ~\$25 million in projected cash, as of expected merger close in March 2019

\* Cervical cancer treatment market size, Share & Trends Analysis Report, Dec. 2018, Grand View Research

\* Head and neck cancer market size, March 2018, Grand View Research

# Projected 2019 Key Milestones

- 1Q 2019: Completion of PDS Biotechnology – Edge Therapeutics merger
- 1Q 2019: Submission of publication on Versamune® mechanism of action
- 2Q 2019: Submission of publication on results of PDS0101 Phase 1 clinical study
- 4Q 2019: Initiation of CIN2/3 registration study
- 4Q 2019: Initiation of partnered (Keytruda®) Phase 2 head and neck cancer study
- 4Q 2019: Initiation of 2<sup>nd</sup> partnered Phase 2 study in advanced HPV cancers

# Post-Combination 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

**Brad Middlekauff**  
Chief Legal Officer



- >20 years of experience in biotech
- In-depth experience with corporate governance, business development and intellectual property strategies




# PDSB Board of Directors

Board of Directors	Affiliation	
Robert Spiegel, MD, FACP <b>Chairman</b>	 Schering-Plough	Former CMO
Sir Richard Sykes, PhD		Former CEO & Chairman
De Lyle Bloomquist		Former Global President
Gregory Freitag		General Counsel, SVP BD, BoD
James J. Loughlin		Former Partner
Frank Bedu-Addo, PhD		CEO
Andrew Saik		CFO
Sol J. Barer, PhD <b>Advisor to the Board*</b>		Former CEO & Chairman

\* Dr. Barer is expected to serve as an advisor to the board of directors



# Developing Broad Product Pipeline with Leaders in I-O

Product	Indication	Partner	Combination	Status
<b>PDS0101</b> <b>(HPV)</b>	Cervical pre-cancer CIN 2/3		Monotherapy	<b>Start Potential Registration Study 4Q 2019*</b>
	Head & neck cancer First line treatment Recurrent/metastatic	 <b>MERCK</b>	Keytruda®	<b>Start Phase 2 4Q 2019*</b>
	Advanced HPV cancers	Confidential	Novel checkpoint inhibitor	<b>Start Phase 2 4Q 2019*</b>
	Cervical cancer Stage IIb-IVa		Chemotherapy	<b>Phase 2 ready</b>
	Anal pre-cancer AIN 2/3		Monotherapy	<b>Phase 2 ready</b>
<b>PDS0102</b> <b>(TARP)</b>	Prostate and breast cancers		Checkpoint inhibitor	<b>Preclinical</b>
<b>PDS0103</b> <b>(MUC-1)</b>	Ovarian, colorectal, lung, breast cancers		Checkpoint inhibitor	<b>Preclinical</b>
<b>PDS0104</b> <b>(Melanoma)</b>	Melanoma		Checkpoint inhibitor	<b>Preclinical</b>

\* These clinical studies are expected to be initiated with funding currently available to the combined company

# Clinical Strategy: Establish PDS0101 Market Leadership and Validate Versamune® Platform

## CIN 2/3 Precancer

- Potential for market-leading potency, efficacy, and safety
- Phase 1/2a study demonstrated *in-vivo* induction of HPV-specific killer T-cells (CD8+)
  - Potentially overcomes limitation of currently available immunotherapies to generate clinically relevant levels of CD8+ cells in humans

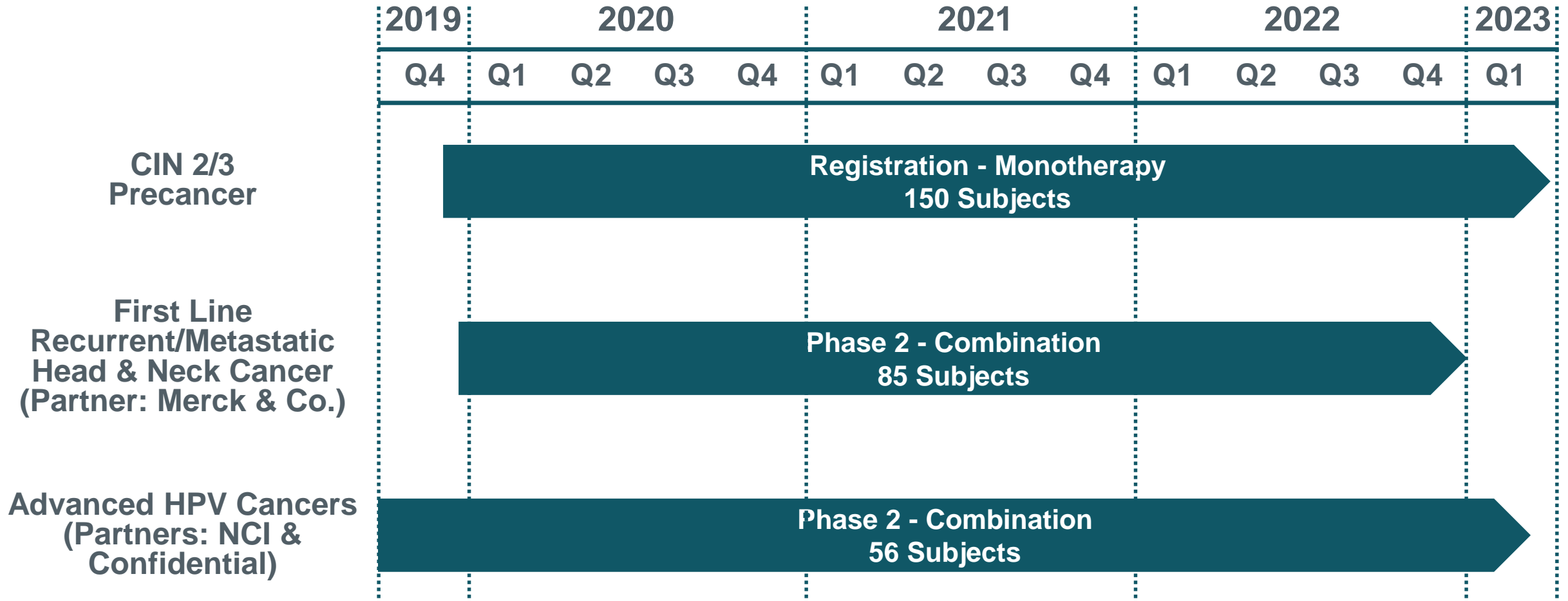
## First Line Recurrent/Metastatic Head & Neck Cancer (HNC)

- Combination with Keytruda® (approved as monotherapy for HNC)
- Potential for HNC leadership position

## Other Potential Studies in Advanced HPV Cancers

- Combination study with chemotherapy standard of care (cervical cancer)
- Combination with Phase 2 next-generation checkpoint inhibitor that demonstrated superior early-stage human efficacy data
  - Preclinical combination data demonstrated superior anti-tumor activity
  - Potential best-in-class I-O therapy across multiple cancer indications

# Projected Clinical Milestones



*Interim analyses will be included in the CIN2/3 and head and neck cancer studies, with sample size and timing to be determined*

# Differentiated Versamune® Platform Activates Key I-O Pathways

Mechanism of Action Overcomes Critical Limitations of Current Immunotherapies To Induce Sufficient Levels of Active Tumor-Targeting Killer T-cells *In Vivo*



- Positively charged nanoparticles designed to overcome known I-O inability to access critical MHC Class I pathway

- Activates powerful & targeted T-cell response via localized stimulation of type I interferon (IFN) genes

- Significantly increases ratio of CD8+ T-cells to immune-suppressive regulatory T-cells (Treg)

- Memory T-cells allow the body to generate tumor attacking T-cells for an extended time period after treatment

## Attributes of Current Immuno-Oncology Technologies

- **Versamune®**
- CAR-T (*ex vivo* only)
- Vaccines (limited)

- **Versamune®**
- STING activators

- **Versamune®**
- Checkpoint inhibitors
- CAR-T

- **Versamune®**
- Vaccines (limited)

# Versamune® Potential: Best-in-Class *In Vivo* Induction & Activation of Tumor-Targeting CD8+ T-Cells

- ✓ Destabilizes cell endosomes
  - Allows antigens to access MHC Class I Pathway
  - MHC Class 1 access necessary to activate CD8+ killer T-cells
- ✓ Induces **localized** upregulation of type I interferons **within lymph nodes (not in blood)**
  - Results in potent activation of CD8+ T-cells – without risk of cytokine storm / systemic toxicity
- ✓ Increasing ratio of CD8+ to immune suppressive cells breaks tumor immune tolerance (tumor's ability to suppress attack)
- ✓ Confirmed induction of memory T-cells



**Broad range of possible applications in oncology by activating targeted immune responses with a wide range of tumor antigens**



**Monotherapy: potent efficacy**  
**Combinations: strong synergy with checkpoint inhibitors**

*Manuscript on mechanism of action submitted to Journal of Immunology by PDS in early 2019*

# Lead Phase 2 Clinical Product: PDS0101

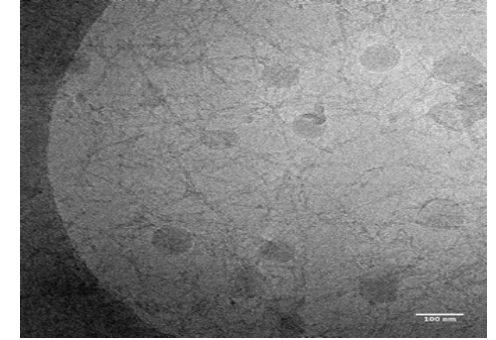
- PDS0101 is comprised of two separate component vials, mixed at bedside: one of Versamune<sup>®</sup>, and another containing a proprietary mixture of six HPV proteins
  - Subcutaneous injection, using off-the-shelf product
- Efficacy is expected to be independent of patient genetic make up
  - Patient T-cell responses in preceding Phase 1/2a clinical study were independent of genetic sub-type (HLA)
- Results of Phase 1/2a clinical study in 12 subjects infected with high risk strains of HPV and Cervical Intraepithelial Neoplasia (CIN):
  - Induced high levels of circulating & active HPV-specific killer T-cells
  - Strong killer (CD8+) and helper (CD4+) T-cell responses
  - Confirmed induction of memory T-cells
  - Excellent safety profile

# Unique PDS0101 Formulation Presents Advantages in Efficacy, Manufacturing, and Administration

Vial of HPV Peptides

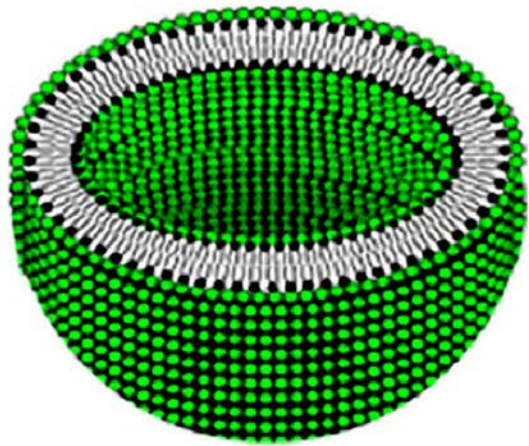


Vial of Versamune®

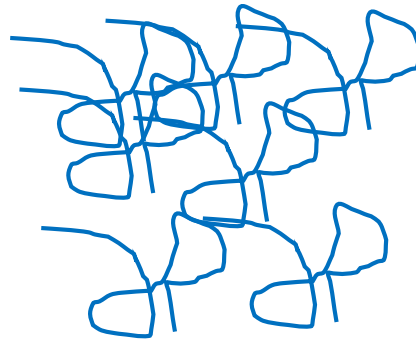


PDS0101 Formulation  
By Electron Microscopy

Vials  
Mixed Bedside



Versamune®



Proprietary HPV  
Peptide Antigens



# Superior PDS0101 Preclinical Activity Vs. Published I-O Data in HPV Pre-cancers

All Companies Have Reported Strong Human Clinical Data

	Inovio*	ISA**	Genexine***	PDS
Antigen Technology	DNA	Peptides	DNA	Peptides
Method of administration	Electroporation	Subcutaneous	Electroporation	Subcutaneous
Preclinical regression of advanced/large TC-1 tumors	Partial (3 doses)*	No**	No***	Complete (Single dose)
Preclinical CD8+ T-cells (ELISPOT - Spleen)	<1,000*	-	<1,000***	2,000-3,000
Human Clinical T-cell response (ELISPOT - PBMCs)	9X greater vs. placebo****	83%*****	100%*****	100%

**PDS0101 induction of high levels of tumor-targeting CD8+ T-cells leads to superior tumor regression efficacy in preclinical models**

**This superior *in vivo* induction of CD8+ T-cells by PDS0101 vs. other I-O technologies is projected to lead to superior efficacy in upcoming Phase 2 clinical studies**

\* Vaccine 2009, January 14, 27 (3): 431

\*\* Science Translational Medicine 2016, 13 April, Vol 8 Issue 334

\*\*\* Vaccine 2009, August 3, 27 (33): 5706

\*\*\*\* Lancet 2015, November 21, 386 (10008): 2078

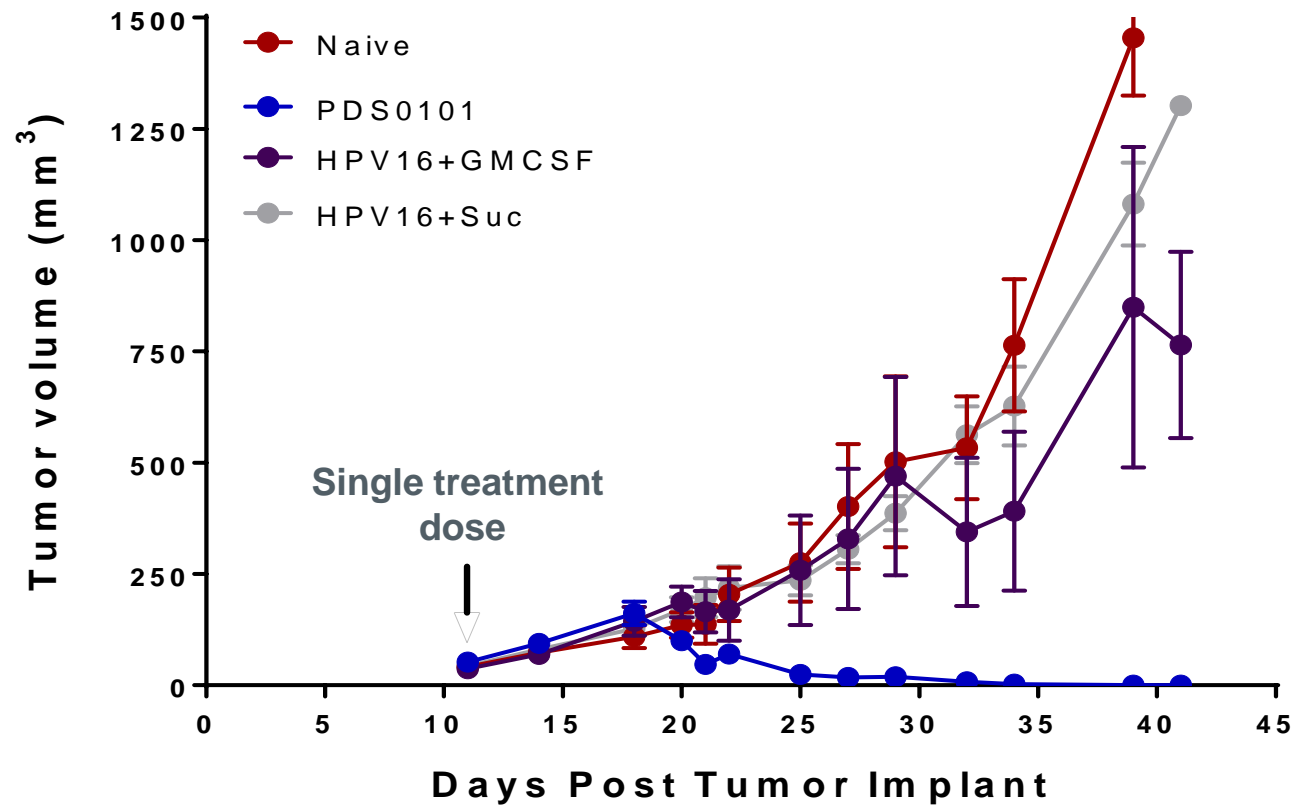
\*\*\*\*\* N ENGL J Med. 2009, November 5, 361, 1838

\*\*\*\*\* Nature Comm. 2014, October 30, 5, 5317



# Rationale for Development of PDS0101

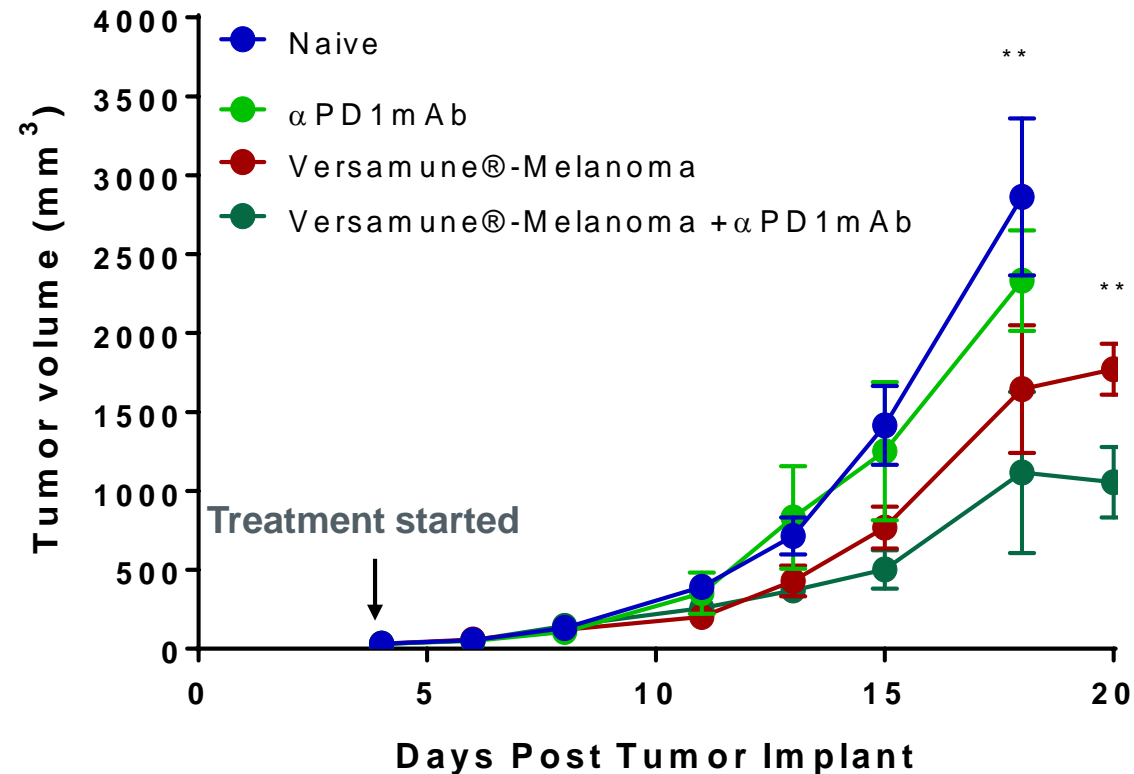
Potent Ability to Eliminate HPV-Positive Tumors in Preclinical Studies as a Result of Excellent *In-Vivo* Induction of CD8+ (Killer) & CD4+ (Helper) T-cells & Infiltration into Tumors



- PDS0101 (Versamune<sup>®</sup> + HPV16) uniquely induces complete regression of HPV-positive TC-1 tumors vs. clinical adjuvant GM-CSF
- PDS0101 induces potent memory T-cell induction, thus preventing establishment of new tumors when challenged by additional tumor cells on Day 50

# Rationale for Combination of Versamune<sup>®</sup> with Checkpoint Inhibitors (αPD1/L1)

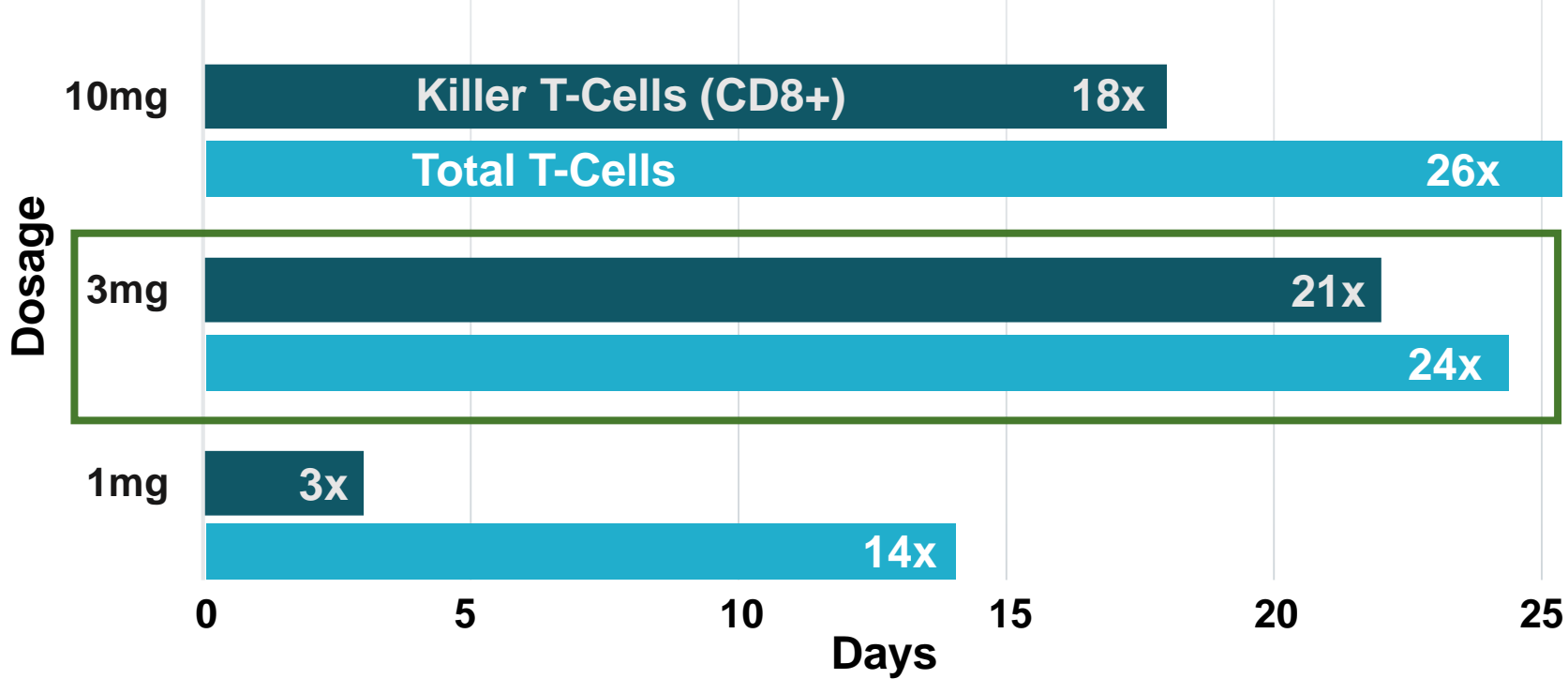
Excellent *In-Vivo* Induction of CD8+ (Killer) T-cells Leads to Strong Synergy with anti PD-1 Antibody in Melanoma Preclinical Studies - Resulting in Significantly Prolonged Survival



- PDS0104 (Versamune<sup>®</sup> + melanoma antigen) induces strong *in-vivo* CD8+ T-cell response and ability to inhibit progression of highly immuno-suppressive B16 tumors
- PDS0104 in combination with αPD1 leads to further enhanced tumor inhibition and survival

# PDS0101 Phase 1/2a Dose Escalating Study

Over 20-Fold Increase in HPV-Specific CD8+ T-Cell Responses Versus Pre-Treatment Levels at Recommended Clinical Doses



## Clinical Study Design

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

- Strong & Measurable *In-Vivo* Induction of HPV-Specific Killer T-cells 14-19 Days Post-Treatment
- Defined dose for Phase 2 and Registration Studies

# Worldwide Burden of Cancer Attributable to HPV

Based on Data Collected in 2012\*

Incidence in Thousands	Anal	Cervical	Head & Neck	Penile	Vulvar/ Vaginal
Asia	17.1	278.0	12.0	5.9	6.3
Europe	6.9	58.0	13.8	2.7	5.1
Latin America	2.9	69.0	1.3	2.0	2.5
N. America	4.5	14.0	8.9	1.1	3.3
World	35.0	530.0	37.5	13.0	20.0

- Incidence of HPV-related head and neck cancer increased by >200% over last two decades; projected to continue to rise\*\*
- Anal cancer incidence increasing by ~2.2% annually; >50% of anal cancers HPV16 positive\*\*\*

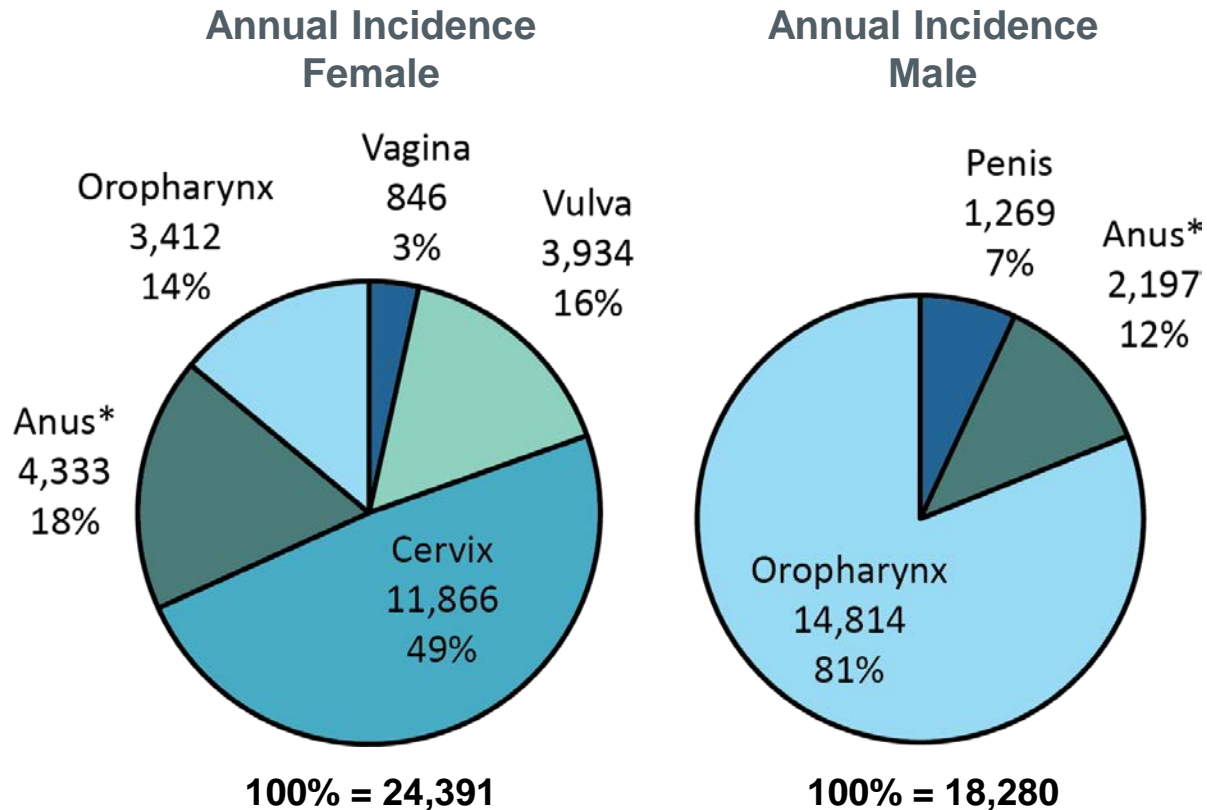
\* de Martel et al, *Int. J. Cancer*: 141, 664–670 (2017) – figures in thousands

\*\* Hoffman-Ruddy, et al., *J Women's Health Care* 2015, 4:2; National Cancer Society (2014) *Oral and Oropharyngeal Cancer*

\*\*\*Grulich et al, *Sexual Health* 9(6) · September 2012

# HPV Market – United States\*

HPV Experts Project Current HPV Preventive Vaccines to have Little Impact on HPV-related Cancer Incidences for Several Decades\*\*



- Incidence
  - ~43,000 HPV-associated cancers
  - ~300,000 CIN2/3 annually
- Cervical cancer
  - Most common HPV-cancer in women
  - Incidence steady
- Oropharyngeal cancers
  - Most common in men

\* CDC Data Brief, August 2018 – based on data collected 2011-2015

\*\* 2016 Report by Dr. Laurie Markowitz, Epidemiologist, U.S. Centers for Disease Control and Prevention

# Key Takeaways From PDS0101 Phase 1/2a Clinical Study

- Strong correlation between preclinical animal data and human data
  - Strong and measurable *in-vivo* induction of HPV-specific killer T-cells 14-19 days after treatment
  - Induction of a memory immune response
- Defined dose for registration study
- Favorable safety profile



**Proceed into  
multiple PDS0101  
Phase 2  
monotherapy and  
combination studies**

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

PDSB IP Strategy Provides Multiple Layers of Technology and Product Protection

- Versamune<sup>®</sup> and associated patents **100% owned** by PDS
- **Four issued** US patents, valid from 2025 – 2033
- **Five issued** international patents (including Europe & Japan)
- **10 total patent families** – provides possible protection of products through 2038
- Patents cover compositions/formulations and methods of use

# Post-Combination Operational/Financial Overview

- PDSB will continue operations in NJ with approximately 10 employees
- Approximately \$25M of net cash\* projected as of expected merger closing
- Cash on hand expected to be sufficient to fund operations into Q4 2020
- Additional funds required to pursue further clinical milestones in 2021-2022

*\* Net of merger transaction expenses, employee severance, and certain other near-term payables*



# Summary: Differentiating Versamune® Technology Presents Potential to Address Key I-O Limitations

	Checkpoint Inhibitors	CAR T-cells	Cancer Vaccines	Versamune®
Induction of CD8+ (killer) T-cells	X	✓ <i>Ex-vivo</i>	X Limited	✓ <i>In-vivo</i>
Overcome tumor immune suppressive mechanisms	✓	X	X	✓
Induction of memory T-cells	X	X	✓ Predominantly CD4+	✓
Systemic toxicity risk	Medium	High	Low to Medium	Low*

\* Based on preclinical toxicology and efficacy studies and Phase 1/2a clinical data

# What Makes Versamune®

## The Next Generation Cancer Immunotherapy?

- **Potential best-in-class activation of tumor-targeted CD8+ T-cells**
  - Stimulating a successful immunologic anti-tumor response requires the following:
    - Ability to present variety of antigens via MHC Class I Pathway
    - Ability to prime the right phenotype of T-cells, tumor-specific killer T-cells (CD8+)
    - Induction of right phenotype of highly active multi-cytokine-inducing CD8+ T-cells - including memory cells
  - Current approaches, such as cancer vaccines, have failed to achieve this goal due to poor simultaneous performance on each of the above critical functions
  - Safety profile ideal for early- and late-stage cancers, in monotherapy or combination
- **Potential best-in-class ability to break tumor immune tolerance**
  - The key to inducing successful therapeutic anti-tumor immune responses is an ability to alter the tumor's immuno-suppressive micro-environment to facilitate its killing

# Differentiated Platform & Data Strongly Support Progression of PDS Phase 2 Clinical Programs

## Versamune® 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 efficacy, potency, and safety
- Well-tolerated subcutaneous administration using off-the-shelf product

## Lead Clinical Program: PDS0101

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- Targeting multiple indications in >\$6 billion HPV cancer market
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# PDSB Wrap-up

1

**Powerful** and safe T-cell-activating immunotherapy platform

2

Potential to **transform** treatment of early- and late-stage HPV-cancers

3

**Validation:** Superior preclinical and clinical data  
Clinical Partnerships with Big Pharma and National Cancer Institute

4

Upcoming **Phase 2 clinical studies**  
Both in monotherapy & combinations with checkpoint inhibitors



**PDS Biotechnology**  
Next Generation Immunotherapies

***A new generation of multi-functional  
cancer immunotherapies***

March 2019