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# Prima BioMed

*Annual General Meeting  
CEO Presentation*

November 25, 2016

ASX:PRR; NASDAQ:PBMD

Marc Voigt



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# 2016 Highlights

## Corporate

- Sound financial management
- Sydys partnering of CVac™
- Significant analyst coverage
- JP Morgan, ASCO, ESMO, SITC conferences
- 3 Patents granted

## Clinical

- First Chinese manufactured biologic dosed in Europe
- TACTI-mel initiated and first patients dosed – encouraging safety data
- AIPAC initiated -first safety, PK and IM data and dose escalation
- AIPAC first and second cohort recruitment complete

## Collaborations

- Ongoing clinical development of our partners GSK and Novartis
- MTA with Yamaguchi /NEC for IMP321
- INSIGHT Trial Announced
- WuXi MoU

# Key Financials

<b>Ticker</b>	ASX: PRR; NASDAQ: PBMD
<b>Market Cap</b>	AUD \$78.72M (23 Nov 16)
<b>Shares on Issue</b>	2,071,537,809 (23 Nov 16)
<b>Options on Issue</b>	77,378,693
<b>Net Operating cash outflow FY 16</b>	AUD \$11.3M
<b>G&amp;A Expenses FY 16</b>	AUD \$6.98M
<b>R&amp;D and Intellectual Property Expenses FY16</b>	AUD \$7.06M
<b>Cash in bank</b>	AUD \$18.2M (3Q,2016)

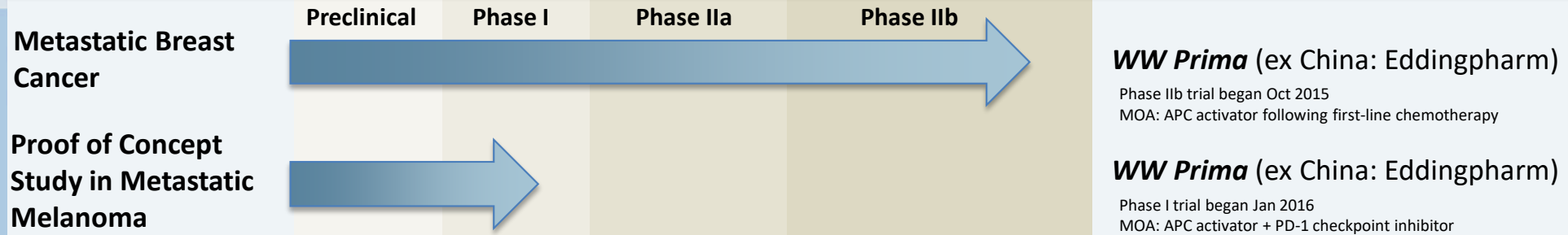
# PROGRAM UPDATE



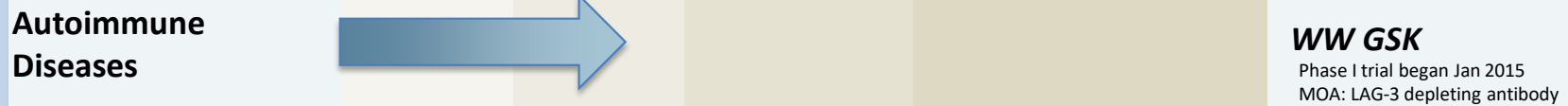
# Pipeline

## LAG-3 Technologies

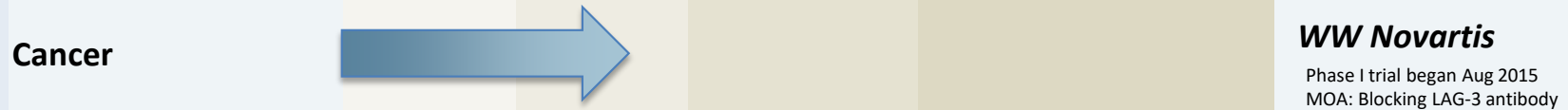
### IMP321



### IMP731

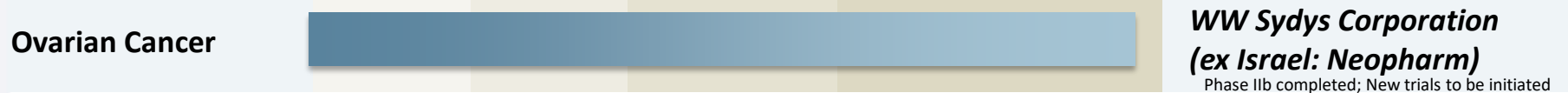


### IMP701



## Autologous Dendritic Cell Therapy

### CVac™



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# IMP321 – one product, many applications

**Chemoimmunotherapy- AIPAC**

**I-O Combination Therapy – TACTI-mel**

**Direct Injection - INSIGHT**

**Cancer Vaccine Therapy – Yamaguchi/NEC**

# AIPAC- Active IMmunotherapy with PAClitaxel

**Chemoimmunotherapy** – adding an antigen presenting cell (APC) activator after chemotherapy treatment to boost immune responses.

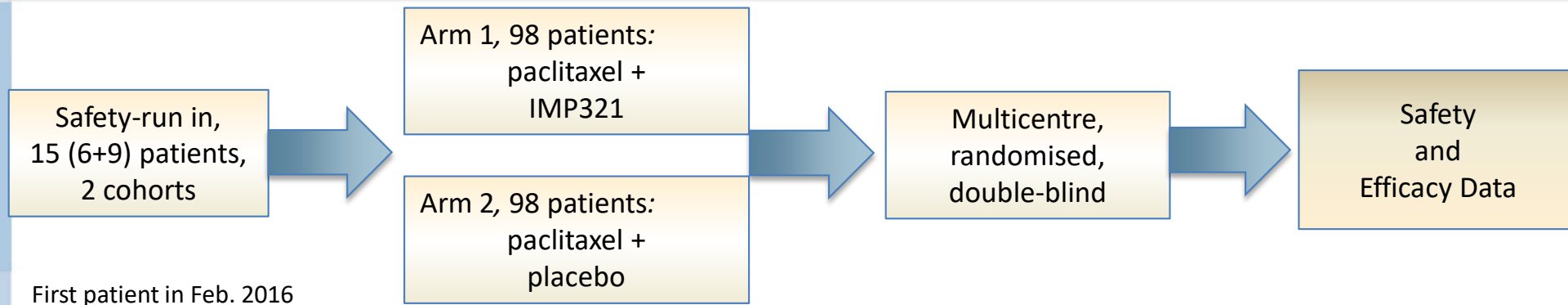
- ✓ Encouraging scientific advice from EMA July 2015
- ✓ Initiated Dec 2015
- ✓ First patient dosed Feb 2016
- ✓ First safety, PK and immune monitoring data June 2016 – dose escalation
- ✓ Second safety cohort recruitment completed
- ✓ First safety run in phase and IM data expected Dec 2016



# IMP321 – AIPAC

## AIPAC trial: Active Immunotherapy PAClitaxel

Phase IIb chemo-immunotherapy in metastatic breast cancer in different EU countries



### Overview

Design	Phase IIb, randomised, placebo controlled, double blinded, multinational
Primary Objective	Run-In: Recommended phase II dose Randomised: paclitaxel + IMP321 vs. paclitaxel + placebo
Other Objectives	Safety, efficacy
Patient Population	Patients with advanced metastatic breast cancer indicated to receive first line chemotherapy with weekly paclitaxel
Treatment	Safety run-in: IMP321 + Paclitaxel Arm 1: Paclitaxel + Placebo Arm 2: Paclitaxel + IMP321
Current Countries	NL, BL, HUN (11 sites active as of Oct 16) , stage II will be conducted in more countries and sites

### Status report

- Initial safety data of the first cohort of patients confirmed the safety and tolerability of IMP321 with no dose limiting toxicities, June 2016
- Recruiting in the safety-run in is completed
- Start of randomised phase expected early 2017

# TACTI-mel Two Active Immunotherapies in melanoma

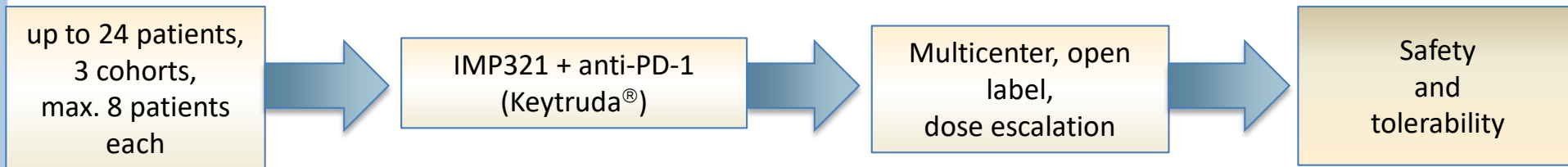
**Combination therapy** – combining an APC activator and a checkpoint inhibitor to kick start the immune response after removing the brake.

- ✓ Initiated Jan 2016
- ✓ Being conducted at 6 sites in Australia
- ✓ First patient dosed May 2016
- ✓ First safety and immune monitoring data Dec 2016 – then dose escalation

# IMP321 – TACTI-mel

TACTI-mel trial: Two Active Immunotherapeutics in melanoma

Phase I study in immuno-immuno combination in unresectable or metastatic melanoma in Australia



First patient in May 2016

## Overview

Design	Phase I, multi-centre, open-label, dose escalation
Primary Objective	Safety, tolerability and recommended dose finding for phase II with pembrolizumab + IMP321 in unresectable or metastatic melanoma
Other Objectives	Pharmacokinetic and pharmacodynamic of IMP321, objective response rate, time to next treatment, progress-free survival
Patient Population	Patients with asymptomatic or suboptimal response after three cycles of pembrolizumab
Treatment	Up to 24 patients 3 cohorts: 1/6/30 mg IMP321; s.c. q2w + pembrolizumab; starting with the 5 <sup>th</sup> cycle of pembrolizumab

## Status report

- 6 clinical sites are approved and all are activated
- Dose escalation decision of the interim data of the first cohort will be expected at the end of this/beginning of next year



## Partner IMP321 trials...

- Yamaguchi/NEC have commenced clinical research using IMP321 as an adjuvant together with their own peptides and adjuvant in solid tumours.
- INSIGHT trial – German investigator sponsored trial in solid tumours testing direct intra-tumoral injection – currently waiting CA and EC approvals

# IMP731 Update

- GSK2831781, GSK's investigational product derived from **IMP731** antibody, in ongoing clinical trial in the context of autoimmune diseases
- To our knowledge, no other company has yet generated an antibody capable of depleting LAG-3 expressing activated T cells
- Up to £64m in total upfront and milestones + royalties
- A phase I study comprising two cohorts has completed in healthy subjects (Part A) and has commenced in patients with psoriasis (Part B)
- Pending results of the phase I study and any future clinical development plans, regulatory filing by GSK potentially between 2021-2025\*

\*[GSK 2015 investor presentation: Slide 108](#)

- Phase I milestone received August 2015
- LAG-525 derived from **IMP701**, in ongoing clinical trials in context of melanoma, lung and renal cancer
- Works by blocking LAG-3-mediated immune down-regulation (removes brake)
- In June 2016, Novartis amended their trial to increase enrollment from 240 to 416 patients and added a third treatment group to the trial that involves treating Japanese pts.
- Estimated study completion date is October 2018

- May 2016 - Sale and Licensing Agreement with Sydys to advance **CVac™** Program
- Prima received a 9.9% equity stake in Sydys for the assets being transferred
- In the event of successful commercialisation of CVac, Prima could receive milestone payments and low single digit royalties on sales
- Provides opportunity for second chance for CVac

# The Market Opportunity for IMP321

Activator and Inhibitor





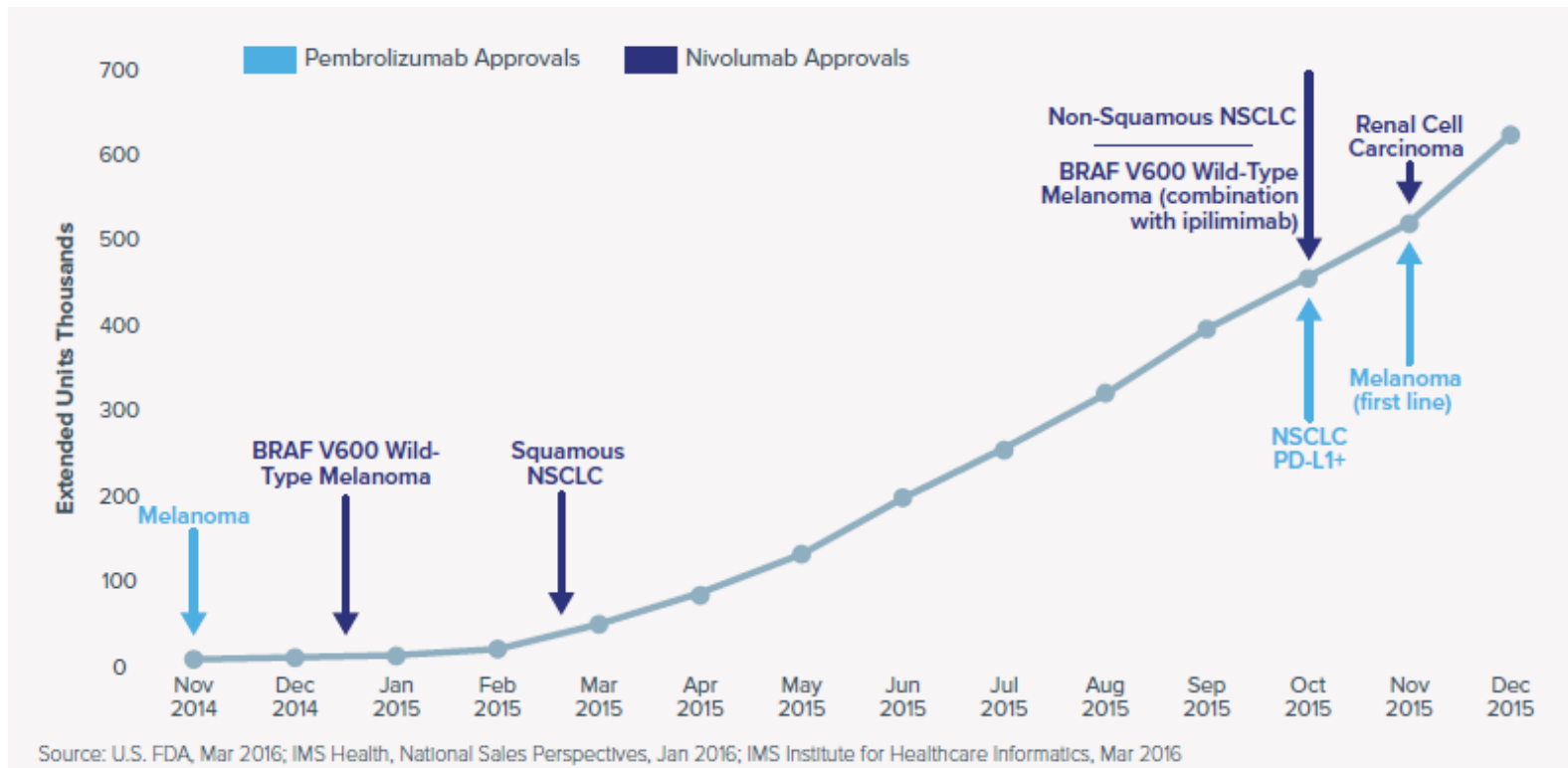
# The I-O market is hot

The global cancer immunotherapy market is expected to reach

- **US\$35 Billion by 2023\***

World-wide **Q2 2016 sales** for the following drugs were

- Yervoy® (US\$241m), Opdivo® (US\$840m), Keytruda® (US\$314m), Tecentriq® (19m CHF)



# The LAG-3 landscape - beyond IMP321

- **Prima** together with its partners, is the **global leader in developing LAG-3 related products (IMP321, IMP701 and IMP731)**
- Increasing global R&D of LAG-3 related product candidates – we are in the right space!

clinical trials	pre-clinical trials
Novartis (Prima's partner)	Agenus
GSK (Prima's partner)	Tesaro
BMS	Sanofi/Regeneron
Merck	Macrogenics
Boehringer Ingelheim	Peregrine Pharmaceuticals
	RXi Pharmaceuticals Corporation/MirImmune, Inc

# IP Portfolio

- 12 patent families providing broad protection across all LAG-3 assets
- Comprises 89 pending or granted applications excluding those licensed to GSK and Novartis
- Protection for methods of use of IMP321 may extend to 2036 excluding SPC or term adjustments
- Regularly review our R&D activities to file new improvements wherever possible

# Opportunity in Metastatic Breast Cancer

- **30%** of breast cancer patients have **metastatic disease** (at diagnosis or more frequently through recurrence)<sup>1</sup> and 2 out of 3 are HR positive<sup>2</sup>
- Metastatic breast cancer (MBC) patients have a **median survival of 2-4 years**<sup>3</sup>
- **5-year relative survival rate** is approximately **22%**<sup>4,5</sup>
- MBC currently remains almost **incurable**<sup>6</sup>
- In the U.S., **annual indirect cost to society** attributable to MBC for women under 65 was estimated to be **over US\$ 572 million** including<sup>7</sup>:

US\$ 270 million

Premature deaths

US\$ 253 million

Lost productivity

US\$ 50 million

Caregiving

The global breast cancer treatment market will reach **US\$17.2 billion** by 2021.<sup>8</sup>

1. O'Shaughnessy J. Extending survival with chemotherapy in metastatic breast cancer. *The Oncologist*. 2005

2. American Cancer Society. (2014). Hormone therapy for breast cancer. *Breast Cancer*. Accessed on September 30, 2014 from <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-hormone-therapy>.

3. Mosher, C. E., Johnson, C., Dickler, M., Norton, L., Massie, M. J., DuHamel, K. (2013). Living with metastatic breast cancer: A qualitative analysis of physical, psychological, and social sequelae. *Breast J*, 19, 3, 285-92.

4. <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage>

5. Madell, R. Metastatic breast cancer: Life expectancy and prognosis. *Healthline*. 2014 at <http://www.healthline.com/health/breast-cancer/metastatic-prognosisF# Overview1>.

6. American Cancer Society. (2013). Detailed Guide: Breast cancer. American Cancer Society. Accessed on September 6, 2014 at <http://www.cancer.org/acs/groups/cid/documents/webcontent/003090-pdf.pdf>.

7. Sorensen, S. V. et al. (2012). Incidence-Based Cost-Of-Illness model for metastatic breast cancer in the United States.

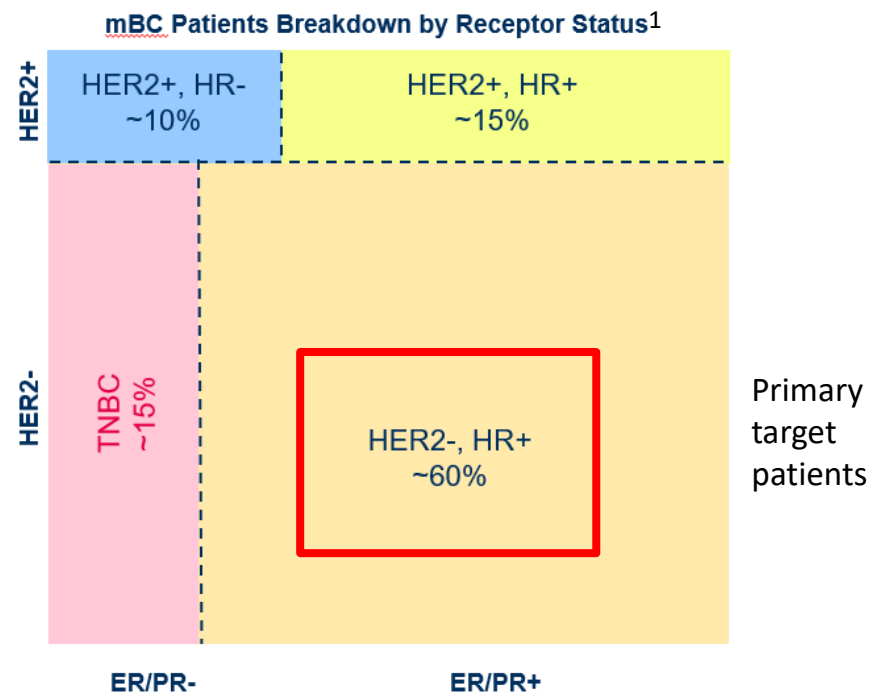
*International Journal of Technology Assessment in Health Care*, 28,

1, <http://dx.doi.org.proxy1.athensams.net/10.1017/S026646231100064X>.

8. [http://www.researchandmarkets.com/research/mg3gms/breast\\_cancer](http://www.researchandmarkets.com/research/mg3gms/breast_cancer)

# Metastatic Breast Cancer Market

- **HER2<sup>-</sup> HR<sup>+</sup>** patient group is our primary target
- Potential label extension is feasible
- AIPAC: study in hormone receptor-positive (ER<sup>+</sup>PR<sup>+</sup>) metastatic breast carcinoma patients with **IMP321 + paclitaxel**



- Global incidence of new cases of all breast cancer is estimated at 1,671,149 cases/yr of which 20% will potentially become metastatic ([Globocan 2012](#))

# Commercial Development Strategy

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# Work in Progress

- Active business development
- Manufacturing discussions ongoing to secure future clinical and commercial supply of IMP321
- International Nonproprietary Name (INN) filed – to be announced 2017
- Active research
- Opportunity for IMP321 approval by EMA – subject to Ph IIb positive results

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# UPCOMING MILESTONES AND SUMMARY





# Upcoming Milestones

## Clinical

- Dec 2016: Safety-run-in results of AIPAC: immuno-monitoring data and safety data; first TACTI-mel data
- Q1 2017 Start of randomised phase for AIPAC
- Q1 2017: TACTI-mel: Dose escalation
- Throughout 2017: TACTI-mel results from different cohorts
- Mid 2017 Efficacy data from AIPAC Safety Run-in (15pts)
- 2017: First results of INSIGHT study

## Other

- Potential milestones from development partners in the coming years
- Continued expansion of IP
- R&D for new products
- Updates regarding LAG-3 landscape
- Ongoing business development

# Summary

- We have multiple ongoing clinical developments with several value inflection points
- We have strong partners with demonstrated commitment to continued development in clinical phases
- We have a solid cash position and sound financial management



# **PRIMA BIOMED**

**NASDAQ: PBMD, ASX: PRR**

*Thank you!*