

INVESTOR UPDATE

by  PRIMA BIOMED

EDITION
AUGUST 2017

20



Marc Voigt, CEO

Message from the CEO

Dear Fellow Shareholders,

As the global leader in LAG-3, we are firmly focused on creating shareholder value through the advancement of our LAG-3 based clinical and preclinical oncology and autoimmune pipeline. We are making meaningful progress on the development of these novel therapeutics targeting clear unmet medical needs and look forward to updating you and the markets with our clinical progress.

We are increasingly confident that the next wave of immune checkpoint inhibitors will be influenced by the LAG-3 mechanism of action, as evidenced at this year's 53rd Annual American Society of Clinical Oncology (ASCO) conference in Chicago, where it was clear that LAG-3 based therapies are now on the way to becoming major components of the future oncology treatment paradigm.

At ASCO, highlighted further in this update, we presented positive clinical data from the safety run-in phase of AIPAC, our European Phase IIb chemo-immunotherapy study in metastatic breast cancer, which showed a very encouraging disease control rate at 87% (see our ASCO Poster [here](#)). Notably, Bristol-Myers Squibb also presented positive efficacy data from one of its nine LAG-3 clinical trials, testing an anti-LAG-3 antibody with an anti-PD-1 antibody.

AIPAC is currently recruiting for the randomisation phase (226 patients) across several European centres. Patient recruitment for the randomised part of the study commenced in January and is expected to be completed in the first half of 2018, with final safety run in data expected in the fourth quarter of this year. Based on our current assumptions, we believe that the primary data readout (PFS) of the randomized part of AIPAC could take place in H1 2019.

TACTI-mel, our Phase I Australian metastatic melanoma trial of IMP321 in combination with KEYTRUDA®, has commenced recruitment of the third cohort. Data from the first cohort were presented in March at the Immune Checkpoint Inhibitors (ICI) Conference in Boston, with encouraging preliminary results. It is anticipated that data from both the first and second cohorts will be presented before the end of 2017 at two major medical conferences and from all three cohorts in the first half of 2018. I encourage everyone to monitor our online company calendar that contains details on upcoming medical, industry, and invest-

or conferences we plan to attend: www.primabiomed.com.au/investor/company_calender.php

Meanwhile, Prof. Al-Batran and his team continue to investigate our lead drug candidate IMP321 in new settings with the initiation of the INSIGHT clinical trial (detailed further in this update). Plus EOC Pharma, an affiliate of our Chinese partner Eddingpharm, is preparing to start new clinical trials now that changes in the local regulatory environment are supporting treatments to address unmet medical needs. The growing appetite for investment in clinical trials targeting immune responses in China further supports the viability of our LAG-3 technology. We are actively supporting EOC in their efforts to start clinical development in China.

In June, to support of the growing reach of IMP321 to patients worldwide, we announced the formation of a new, high calibre Clinical Advisory Board (CAB) that will serve as a strategic resource to Prima in advising the Company on the regulatory and clinical development strategy for AIPAC and our other clinical trials.

We acknowledge that this positive momentum has not been fully reflected in our recent share price performance and the frustration this is causing shareholders, many of whom have been longstanding supporters. Ultimately sentiment around the Company will be driven by the clinical progress of our pipeline and data generation, our partners, and other pharma companies developing LAG-3 related products.

For example, one of Prima's pharma partners, GlaxoSmith-Kline (GSK), recently announced a clinical reorganisation, cancelling several of its programs. While this may have negatively impacted sentiment, it should be noted that the LAG-3 program in partnership with Prima was not affected (see their [presentation](#)).

[Continued on p. 2]

>> In this Issue:

- Message from the CEO
- 2017 ASCO Review

[Continued from p. 1]

In fact, this may be a net positive for Prima in that GSK has discontinued two new biologics targeting general inflammation (IL-6 and CCL20 mAbs) that otherwise might have competed internally for resources with Prima's IMP731 program in auto-immune diseases.

We maintain regular dialogue with the regulatory authorities in the U.S. and Australia to monitor the trading in our shares, however it should be noted that the market's reaction to our own and other industry news is in principle out of our control. We remain grateful for the ongoing and continued shareholder support as well as patience; we remain confident that we have the right assets and people in place to deliver improved value for shareholders over time.

Finance Update

The 2nd Novartis milestone payment of US\$1 million has now been transferred and received by Prima's accounts, and we expect to receive further milestone payments from our existing partnerships. Prima's financial position has also been strengthened by the recent U.S. capital raise of US\$5 million (A\$6.5 million), our first capital raise using our American Depository Shares (ADS) since listing on NASDAQ in 2012.

The financing was priced at a discount of 18% to the prior day's closing share price and included 75% warrant coverage, both of which were inline in with terms of similar financings for comparable U.S. listed microcap biopharmaceutical companies.

This capital infusion has provided important financial headroom to fund our clinical development program and brought several U.S. healthcare specialist institutional investors to our share register. The process also significantly improved our profile among a broader base of specialist healthcare funds, a key strategic objective of the Company.

Our cash balance as at 30 June 2017 was A\$12.3 million. The additional proceeds received in July from the U.S. capital raise, the milestone payment from Novartis, and an R&D tax refund in Australia have extended our operational cash reach well into the last quarter of calendar year 2018, based on current management forecasts (and which do not include potential additional milestone payments from existing partnerships).

Initiation of INSIGHT Clinical Trial

It's evident that our lead product, IMP321, is gaining traction on the global stage as an innovative product candidate with many therapeutic applications beyond cancer treatment. The ground-breaking research and development conducted under the stewardship of our CMO and CSO in Paris, Dr Frédéric Triebel, led to the collaboration between Prima and the Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany (IKF). In July, a new investigator driven clinical trial, called INSIGHT, received the regulatory and ethical approvals to initiate this trial.

Lead Investigator, Prof. Dr Salah-Eddin Al-Batran, Medical Director of the IKF, and his team will explore different routes of administration of IMP321 in solid tumours present in up to 40 patients. This marks the first ever investigation of whether direct injection of IMP321 into a solid tumour can activate the antigen presenting cells located inside the tumour to boost the body's immune response. As an investigator-led trial, it currently requires no material resources from Prima, and we look forward to keeping you updated on this exciting study.

Lastly, we continue to explore new business development opportunities that would leverage our LAG-3 expertise and pipeline, and I hope to be able to update you on some of these initiatives in the months to come.

2017 ASCO Review - Frederic Triebel



Dr Frédéric Triebel

According to figures from consulting firm GlobalData (as at May 2016), the current total immune-oncology market is worth more than \$19 billion and will rise to \$34 billion over the next seven years¹. The American Society of Clinical Oncology (ASCO) is the most prestigious global oncology conference in the world, with the 2017 event in Chicago attended by more than 35,000 delegates from more than 100 countries.

At the conference, it was clear that the LAG-3 based concept and approach of directly activating and harnessing

the immune system is gaining traction as the new frontier in cancer treatments. Prima's IMP321, in addition to KEYTRUDA[®], represents one of the first proposed active immunotherapy drugs in which the patient's own immune system is harnessed to respond to a burst of tumour antigenic debris created by a chemotherapy injection.

We are witnessing wider acknowledgement that checkpoint inhibitors enable the immune system to mount a more effective anti-tumour response in a patient, as evidenced by the number of pharma companies with clinical stage LAG-3 programs (BMS, Novartis, Merck, Regeneron and Boehringer Ingelheim GmbH). Merck's KEYTRUDA[®] alone is forecast to generate nearly \$7 billion by 2020², while BMS' immunotherapy drug OPDIVO[®] for lung and renal cancer has just been added to the Pharmaceutical Benefits Scheme in Australia under one of the largest ever listings, costing the government A\$1.1 billion annually³.

We are only scratching the surface of the huge potential harnessed by checkpoint molecules for drug development for cancer, as well as autoimmune diseases. We have a long way to go in understanding LAG-3 biology further, though the growing and positive experience in the clinic to date is boosting the industry's excitement for the immunoncology prospect.

We encourage you to read a recently published report in [European journal MedNous](#), written by Dr. Triebel, on the advances in the immuno-oncology field as represented at this year's 2017 ASCO Conference.

1) www.globaldata.com/store/report/gdhc057poa--immuno-oncology-strategic-insight-multi-indication-and-market-size-analysis/
2) www.globaldata.com/store/report/gdhc057poa--immuno-oncology-strategic-insight-multi-indication-and-market-size-analysis/
3) www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt073.htm

Company Calendar

September 08-12, 2017	ESMO, European Society for Medical Oncology Congress, Madrid, Spain
October 31th, 2017	World Immunotherapy Congress, Basel, Switzerland. Frédéric Triebel is speaking about TACTI-mel, two ACTIVE immunotherapies in melanoma: combination of an APC activator (IMP321 or LAG-3Ig) with Pembrolizumab at 5:50 PM.
November 08-12, 2017	SITC, Society for Immunotherapy of Cancer, National Harbor, MD, USA
November 2017	Annual General Meeting in November 2017

Follow Prima's progress

Prima BioMed is dedicated to maintaining consistent and clear communications with our investors. In addition to our quarterly newsletter, we encourage our shareholders to continue following Prima's progress in a number of ways:

► **www.primabiomed.com.au**

The company website is a treasure trove for those in search of details about our company, our management team, and archived information. We encourage everyone to check it out regularly.

► **www.clinicaltrials.gov**

Prima registers all of our clinical trials, and the details of enrolling doctors, on the ClinicalTrials.gov website, a service of the United States National Institutes of Health. This register is the largest such repository of clinical trial information around the world.

Our ClinicalTrials.gov ID for our trials are as follows:

- TACTI-mel trial is NCT02676869
- APAIC is NCT02614833

► **Twitter**

twitter.com/PrimaBioMed

► **Facebook**

www.facebook.com/PrimaBioMed

► **LinkedIn**

www.linkedin.com/company/prima-biomed-ltd-

Prima BioMed – Fast Facts

Listings

Australian Securities Exchange (ASX), NASDAQ

Stock Codes

ASX: PRR, NASDAQ: PBMD

Issued Capital

2.34 billion ordinary shares (31st July)

Issued ADR's

8.6 million (28th July)

Market Capitalisation

A\$53.9 million (US\$43 million) (31st July)

Board of Directors

Ms Lucy Turnbull, AO	Non-executive Chairman
Mr Albert Wong	Non-executive Deputy Chairman
Mr Marc Voigt	Executive Director and Chief Executive Officer
Dr Russell J Howard	Non-executive Director
Mr Pete A Meyers	Non-executive Director

Senior Management

Prof Dr Frédéric Triebel	Chief Medical Officer and Chief Scientific Officer
Deanne Miller	Chief Operating Officer, General Counsel and Company Secretary