

# INVESTOR UPDATE

by  **PRIMA BIOMED**

**EDITION** **17**  
MAY 2016



*Lucy Turnbull, AO*

## Message from the Chair

Dear Fellow Shareholders,

The Prima board and management recently announced to you the successful partnering of CVac™ with US based Sydys Corporation (SYYC) that will see the continued clinical development of the CVac program in ovarian cancer and other indications. Our team has worked hard to devise an entrepreneurial solution that we hope will build on the historical progress and results generated to date by Prima.

We are confident that the founder of Sydys, Mr Joseph Hernandez, has the necessary expertise to move this technology forwards. In this newsletter we explain more about the structure of this agreement and what it means for Prima, while also introducing you to Mr Hernandez and Sydys. I commend both parties on the way they have worked together to come up with a program that intends to see this product continue in the clinic.

In the March 15 edition of the Clinical Cancer Research journal, the results of one of our academic collaborations involving IMP321 were published and coauthored by our Chief Scientific Officer Dr. Frédéric Triebel, with scientists at the Ludwig Centre for Cancer Research at the University of Lausanne, Switzerland. We outline further details of some of our collaborative trials for you in this edition.

Our clinical initiatives continue to progress well and we have employed a new clinical director, Christian Mueller, to oversee the coordination of these programs. Christian will be based in Germany where our larger AIPAC trial is based, but he will also be responsible for our global programs.

With the successful divestment of the CVac program, our team is focused fully on both our current R&D programs in the LAG-3 field and exploration of potential new opportunities. Both Marc Voigt and Dr Frédéric Triebel have been actively attending conferences to promote discussions and awareness of our company and LAG-3.

Please watch our new video on LAG-3 and more specifically the mode of action of IMP321 on our website at

► <http://primabiomed.com.au/products/LAG-3>  
or click [here](#) to take a look.

Yours sincerely,

**Lucy Turnbull**  
Chairman Prima BioMed Ltd



*Marc Voigt, CEO*

## Message from the CEO

Dear Fellow Shareholders,

Following extensive discussions we are pleased to have found a team of experienced and entrepreneurial management at Sydys Corporation who will continue the clinical development and progression of CVac. This agreement is not the typical kind of licensing transaction many of you might be accustomed to reading about in industry news and we'd like to explain it to you in more detail.

Sydys Corporation has been repurposed by New York biotechnology entrepreneur Mr Joseph Hernandez specifically for continuing the CVac development program. Joe has significant experience raising capital in the US for the commercialisation of biotechnology assets. He is in the process of bringing very experienced senior management on board. For those that are interested in continuing to follow the CVac journey please follow its progress at [www.sydyscorp.com](http://www.sydyscorp.com).

Prima's former Chief Technical Officer, Dr Sharron Gargosky will also join Sydys as a strategic advisor to ensure the technology transfer is as seamless as possible. Her experience with CVac and the lessons learned over the past 15 years will be a valuable asset. The combined experience of the team members at Sydys and the continuity of institutional knowledge that Sharron will provide should maximise the chance of progressing CVac through further clinical development

In this "spin out" Prima will transfer its contracts and some inventory and equipment to Sydys but the arrangement primarily involves the licensing of CVac IP and know-how. There will be a combination of development milestones, commercial milestones and royalties on sales that will be payable if predetermined targets are met.

*[Continued on p. 2]*

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The total potential value of these undisclosed milestones could be in excess of A\$400M (US \$293M), payable later in the development phase. In addition, this transaction allows us to fully focus on the LAG-3 related product candidates.

This type of licensing structure is not uncommon with technologies that have a higher level of development risk. Such a transaction is usually a compromise to ensure a fair balance between risk and reward for both parties, an amicable and entrepreneurial solution.

Sydys' management is well qualified and capable of continuing the development path for CVac. We are confident CVac will benefit certain subpopulations of patients and also potentially work in combination with other therapies. It may take Sydys some time to raise the required funds, seek new regulatory approvals and commence new trials, so we encourage you to watch out for their news. Thank you to our shareholders for facilitating the development of CVac to this point in its journey. There is a "CVac Q&A" section within this newsletter which we hope will answer any questions related to this agreement.

#### Financial Update

Prima remains in a solid cash position, with approximately \$22.8M cash in the bank as at 31 March 2016, sufficient to see us through to at least mid-calendar 2017. R&D expenditure has increased during the past quarter as we continue with the rollout of our IMP321 clinical trials in Europe and Australia. We continue to receive good interest from analysts at independent investment banks in the US market. Reports remain positive and we have recently received coverage from Maxim. Our share price has remained relatively stable throughout the first quarter of the year despite the relatively poor performance of the stock markets in general and the Nasdaq Biotechnology Index specifically. While there is significant room for improvement, this is encouraging.

*Dr Frédéric Triebel  
presenting at the 6<sup>th</sup>  
Australasian Vaccine and  
Infectious Diseases  
Conference in Brisbane  
20-22 April 2016*

#### Personnel Changes

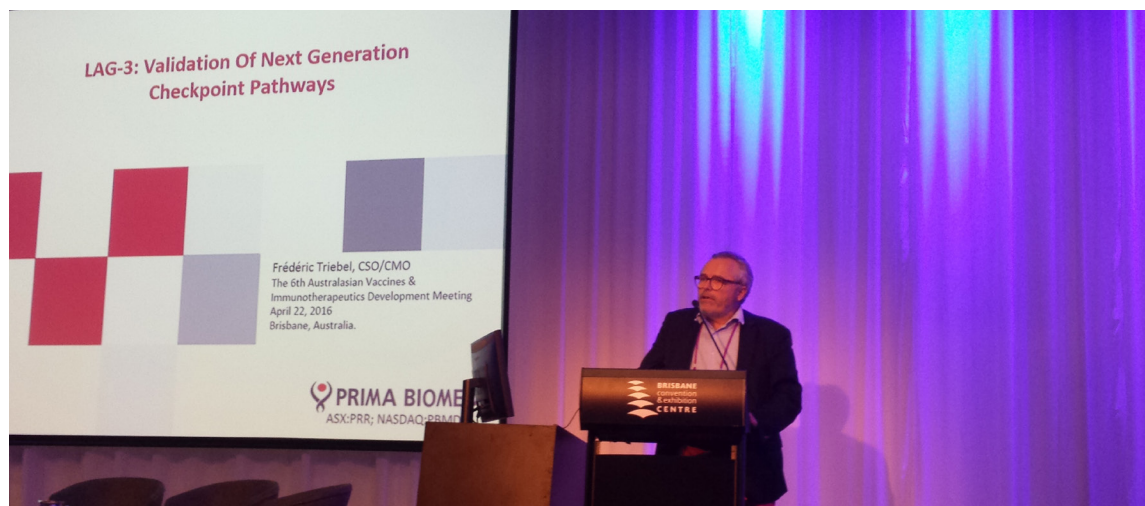
This year has seen some movement in our global management team with several staff commencing or anticipating maternity leave and some staff moving on to new challenges. I'd like to welcome Ms Megan McPherson as finance director in our Sydney office. I also look forward to Christian Mueller joining our team in Berlin as our new clinical development director at the beginning of June.

#### Operations

All other aspects of the business are progressing well. I encourage you to read updates about our clinical, and academic collaborations in the remainder of this newsletter. In February I travelled to China with Frédéric to meet with our partners Eddingpharm and WuXi in Shanghai. We recently announced that the IMP321 product manufactured by WuXi was the first protein manufactured in China to receive approval for administration in Europe. In April Frédéric travelled to Brisbane as an invited speaker to meet with Australian Scientists and present at the 6th Australasian Vaccine and Infectious Diseases Conference. Frédéric also travelled to London to present at the Immune Checkpoint Modulation & Combination Therapies Conference. Here he also had the opportunity to participate in a round table panel discussion on the future of immune checkpoint modulation and combination therapies.

We now look forward to focusing on executing our clinical trial program, on some new and exciting areas of the business and bringing you updates in these areas throughout the year

**Marc Voigt**  
CEO Prima BioMed Ltd



## CVAC Q&A

### **What is the timeframe for completing the transaction and what are the conditions that might prevent its consummation?**

Before this transaction was announced, multiple steps including due diligence had already been completed.

Relevant third parties have been informed and have granted consent where necessary. The customary conditions for closing such as transfer of assets and documentation remain.

Payment of any future milestones will of course be entirely dependent on achievement of undisclosed pre-commercial and commercial milestones as a result of further clinical trials.

### **Who is Sydys and who is running the company?**

SYDYS has the purpose of continuing to develop CVac.

The venture is being spearheaded by experienced US entrepreneur Joseph Hernandez based in New York. Mr Hernandez has successfully created multiple biotechnology spin offs using the reverse merger approach.

Prima CEO Marc Voigt will join the Board of Directors along with Mr Hernandez.

### **What is Sydys's financial position and how does it intend to raise the financing?**

Initial funding from majority shareholder Joseph Hernandez will establish the new operations as a biotechnology company and allow capital raising activity in the US in order to continue further clinical trials.

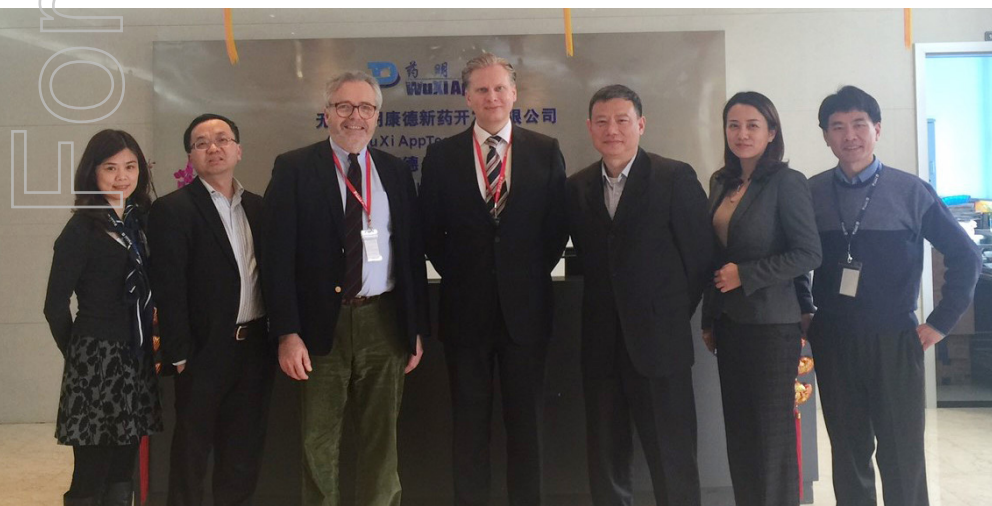
Mr Hernandez is very experienced and well connected with various individuals and funds in the US. He is the founder and chair of five early stage biotechnology /pharmaceutical companies and connected to venture capitalists in New York. His previous transactions include Microlin Bio, Ember Therapeutics and Stryker.

Prima cannot specifically comment on Sydys' fund raising strategy other than to say that their management has significant expertise in this area.

### **What are the expected timeframes around potential milestone payments?**

The milestone events which trigger payments contain both commercial and development milestones. Dependent on the development strategy, substantial milestone payments could be received over the coming years.

Of course the eventual commercialisation of CVac would trigger the majority of these payments. Specifics regarding the milestones are commercial in confidence.



*Second from left: Chris Chen Ph. D., CEO of WuXi Biologics. Dr Frédéric Triebel and Marc Voigt with staff at WuXi Biologics.*

## Meet Joseph Hernandez, Executive Director of SYDYS CORPORATION

### Can you tell us a bit about your background?

I have an educational background in both science and business administration and entrepreneurship. I started my career working in marketing and product development with a number of pharmaceutical companies including Merck and Affymetrix and worked my way up to President and CEO roles. I've been an advisor to the Ministry of Foreign Affairs of Denmark and I have held board and chair positions in a variety of companies including hospitals and biotechnology companies. I therefore have a breadth of experience from private, public, not for profit and government backgrounds. I'm very passionate about science and I have great people skills.

### Can you tell us how you became interested in Prima?

Originally I contacted Prima to see if they were interested in one of the technologies I was spinning out. After learning more about their CVac technology I became really excited. I could see promise in the data they had generated and felt the connections I had in the New York investment bank market could really help to raise the further capital needed for further clinical trials in the US.

### What are some of the other technologies or companies you have developed?

I've been involved in developing a wide range of technologies including COX2 inhibitors, HPV diagnostics, biological sensors, osteoarthritis products and my most recent company is developing microRNA technology for oncology diagnostic and therapeutic applications.

### How long before you resume trials?

We will issue guidance on this in the coming months. Now the agreement has been finalised our priority is to begin the necessary planning for capital raising and new trial designs.

## Do we have your correct email address?

We recently checked the email addresses registered against shareholders at our share registry, Boardroom Ltd, and found that over **8%** of them were no longer valid. If Boardroom has a valid email address for you then you can receive all communication from Prima, including investor newsletters like this one, electronically. To add an email address to your account, or change the email registered there, please call Boardroom Ltd on **1300 737 760** within Australia or **+61 2 9260 9600** outside Australia.



## Academic Collaborations Update

In the past, Immutep has been associated with a number of academic collaborations using IMP321 as a vaccine adjuvant (a compound administered together with another treatment to help boost an immune response).

Three investigator led, human trials, P006, P007 and P009 have been completed with IMP321 in melanoma, the most recent of which was published in the peer reviewed journal, *Clinical Cancer Research* (Vol 22(6):1330-1340).

In these trials a total of more than 50 patients have been treated. While these trials provide valuable additional data in safety and immune responses, it is important to note that the treatment protocols are different to that of the newly planned Phase I melanoma trial we call TACTI-mel.

When IMP321 is used as an adjuvant, it is used at a low dose to help improve existing immune responses to specific antigens. Similar to the above melanoma collaboration, NEC in Japan are sponsoring the conduct of trials by Yamaguchi University with IMP321 as an adjuvant in solid cancers in Japan. Preclinical testing of IMP321 in mouse models was completed in 2015. The latest results from their study were featured in the April 2016 edition of *Cancer Science* [Cancer Science Vol 107 (4):398-406]. As we

announced on the 11 December 2015, following the preclinical tests we have entered into a material transfer agreement to provide IMP321 material to Yamaguchi for their phase I human trials. This trial is independent of Prima's AIPAC and TACTI-mel trials and are being conducted by Yamaguchi with material supplied by Prima.

In our chemoimmunotherapy trials in metastatic breast cancer, a high dose of IMP321 is given to increase the number of monocytes that are circulating in the blood and to help boost overall systemic immune responses to lots of cancer antigens from the debris created by the chemotherapy agent. In the checkpoint combination trial in melanoma, we are looking to boost the overall immune response (ie activating immune responses) as well as removing the brakes from the immune response by using a PD-1 checkpoint inhibitor.

These are just three very distinct ways (low dose, high dose and combination), in which IMP321 is being used, meaning it is quite a versatile recombinant protein. By collaborating with academic partners such as in the melanoma studies and those with NEC, our partners gain valuable data to help support our understanding of how IMP321 works.

## Clinical Update

All of our current trials are progressing as expected. The first cohort of patients on our AIPAC chemoimmunotherapy trial for metastatic breast cancer in Europe has now been filled. First data from this first cohort of patients is expected in June this year.

TACTI-mel, our Australian melanoma trial is also progressing with the investigator kick off meeting held in Melbourne in February. Several sites have now been initiated in Queensland and Victoria. More sites will soon follow in Perth and South Australia. We look forward to bringing you updates on this trial later throughout this year.

## Coming up for Prima in Calendar Year 2016

- Ongoing Phase IIb trial with IMP321 (AIPAC)
- Ongoing Phase I trial with IMP321 (TACTI-mel)
- Ongoing Phase I trial for IMP701
- Ongoing Phase I trial for IMP731
- Continued expansion of intellectual property
- R&D for new products
- Ongoing: Business development

## Company Calendar

May 26, 2016

Canary Stocks to Watch Roadshow, Sydney, Australia

June 03-07, 2016

ASCO 2016, Chicago, Illinois

## 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](http://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](http://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](https://twitter.com/PrimaBioMed)

### ► Facebook

[www.facebook.com/PrimaBioMed](https://www.facebook.com/PrimaBioMed)

### ► LinkedIn

[www.linkedin.com/company/prima-biomed-ltd-](https://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 – Ordinary shares

2.06B (approximate as at 10th May 2016)

### Issued ADR's

21.4M (approximate as of 10th May 2016)

### Market Capitalisation

90.7M (approximated as of 10th May 2016)

## 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

**Tom Bloomfield**

Company Secretary

**Prof Dr Frédéric Triebel**

Chief Medical Officer and  
Chief Scientific Officer

[www.primabiomed.com.au](http://www.primabiomed.com.au)