

## **PRIMA BIOMED DISCUSSES Q3 OF FISCAL YEAR 2014 RESULTS AND CVAC PROGRAM UPDATE – EARNINGS CALL TRANSCRIPT**

### **Executives**

Matthew Lehman, Chief Executive Officer  
Marc Voigt, Chief Financial Officer  
Sharron Gargosky, Chief Technical Officer

### **Analysts**

David Langsam, Biotech Daily  
Adam Stoddard, Stoddard Capital

Prima BioMed (ASX:PRR, NASDAQ:PBMD; Deutsche Börse:Y91B.F) Q3 of Fiscal Year 2014 Results Earning Call and CVac Program Update Discussion 6<sup>th</sup> May 9:00am AEST

**Anita Green – Moderator:** Good day ladies and gentlemen, and welcome to the Prima Biomed Ltd Quarterly conference call for the third quarter ended 31<sup>st</sup> March 2014. My name is Anita and I will be your moderator today. At this time all participants are on a listen-only mode. We will conduct a question-and-answer session towards the end of the conference. At which time, if you wish to ask a question, you will need to press star (\*) followed by the number one on your telephone keypad.

Along with me today is Mr. Matthew Lehman, Prima's Chief Executive Officer, Dr. Sharron Gargosky, Chief Technical Officer, and Marc Voigt, Chief Financial Officer.

Before we begin, I'd like to remind you that, during this call, forward-looking statements will be made that are subject to risks and uncertainties that may cause actual results to differ from the results discussed in the forward-looking statements. Reference to these risks and uncertainties are disclosed in Prima's public announcements to the ASX and disclosure filings with the U.S. Securities and Exchange Commission.

After some prepared remarks by the management team, we will open the lines for questions. To ask a question, you will need to press star followed by the number one. I would now like to turn the call over to Prima's CEO, Mr. Lehman. Please go ahead.

**Matthew Lehman - CEO:** Thank you, Anita. I appreciate the intro. Hello, everyone, and thank you for joining us today. The last quarter was a very busy one for Prima as we have prepared to re-launch our CVac clinical development program. Before turn over to Dr. Gargosky for a more detailed discussion about our clinical and R&D program, I do want to highlight the upcoming data points and our CVac clinical development objectives.

As we recently announced, the final CAN-003 progression-free survival (or “PFS”) analysis has been accepted for oral presentation at the American Society for Clinical Oncology annual meeting. Dr. Heidi Gray, the study’s lead investigator will present the final PFS analysis as well as an update on overall survival as we continue to monitor patients. In accordance with ASCO policies, the data is embargoed until made public via ASCO. The study abstract will be made public on May 14<sup>th</sup> at 5:00pm East Coast U.S. time. We will issue an announcement to the ASX to coincide with ASCO’s public release of the abstracts. Dr. Gray’s oral presentation is scheduled for May 31<sup>st</sup> at 2:27pm Chicago local time. After the ASCO presentation, Prima plans to hold a teleconference and webcast to discuss the data with Dr. Gray and Dr. Brad Monk from our clinical advisory board.

In addition to the ASCO presentation, we expect that the CAN-003 trial will be published in a medical journal this year and Dr. Gray has also been invited to present trial data at the 2014 Western Association of Gynecologic Oncologists Annual Meeting to be held June 25-28 in California. Later this year, based on our current projections, we anticipate that the CAN-003 overall survival data will be mature enough for analysis in about the fourth quarter of calendar year 2014.

Overall, I am pleased that we will have multiple upcoming opportunities to share new CVac data with the scientific and medical communities.

Along the same lines, I am also pleased that we have been able to recruit an esteemed and high-profile team of gynecologic oncologists to our clinical advisory board. In addition to Dr. Monk, Professors Eric Pujade-Lauraine in France, Christian Marth in Austria, and Ignace Vergote in Belgium recently joined Jonathon Berek from Stanford, Walther Kuhn in Germany, and Jeffrey Goh in Australia. We are grateful to have the European additions to the clinical advisory board as we focus our clinical development in the region. Our clinical advisors help Prima with optimizing our clinical trial design, our regulatory strategy, recruitment of study centers and patients, and generally increasing the awareness of the CVac program in ovarian cancer. I encourage our listeners to take a look at our recently issued shareholder newsletter, which includes a profile of our newest clinical advisory board members.

As well as our clinical development progress, we have made business development a priority at Prima. Last quarter, we finalized our agreement with Neopharm Group to license CVac rights in Israel and Palestine. This was a good milestone for the product as the first commercial partnership for CVac. And we are also looking at complementary technologies

and products that would be value accretive to our shareholders, especially those transactions that help us consolidate our leadership in the emerging field of cancer immunotherapy.

And I will now turn over to Dr. Gargosky to give a more detailed update on our R&D activities, and then Mr. Voigt who will review the finances.

**Sharron Gargosky, PhD – CTO:** Thank you, Matt, and hello as well.

To pick up where Matt left off, and to remind our listeners, we learned a great deal about CVac from our CAN-003 trial and this data has served as the basis for our continued clinical development in ovarian cancer. The final PFS data will be the subject of Dr. Gray's ASCO presentation.

Just a couple weeks ago, we announced that the first patient was enrolled on Part 2 of our CAN-004 clinical trial. This is a 210-patient, phase 2, randomized trial of CVac versus standard of care in platinum-sensitive epithelial ovarian cancer patients in second remission. The primary endpoint of the trial is overall survival, with progression-free survival as an important secondary endpoint. As we move forward, as an administrative matter, I would like to notify our listeners that we intend to formally separate CAN-004 into two separate protocols. Instead of Part 1 and Part 2 of that protocol, we will be giving a new protocol number – CAN-004-B – to the new 210-patient cohort of patients in second remission. For a period of time, in various regulatory and public communications, you may see CAN-004 Part 2 and CAN-004-B used interchangeably.

There are now 16 trial sites actively recruiting patients in Europe for CAN-004-B. We anticipate scaling the trial up to about 60 centers in total to meet our desired clinical trial timelines. To date, the protocol has been approved by regulators and ethics committees in Belarus, Belgium, Bulgaria, Latvia, Lithuania, Poland, and Ukraine. We intend to make the required submissions soon and include centers in Austria, Germany, and France.

As most of you may know, we benefit from multi-million euro grant support from the Saxony Development Bank in Germany and a cost-effective manufacturing collaboration with the Fraunhofer Institute of Cell Therapy and Immunology in Leipzig. These arrangements allow us to conduct high quality clinical trials with leading European centers and the data we generate will support clinical development in multiple geographies worldwide.

Regarding regulatory matters in Australia and the U.S., as a reminder, neither the TGA nor FDA provide approval of a protocol in the same sense as European countries. In Australia, the CAN-004 protocol, as amended, has been approved by Human Research Ethics Committees of the sites and the TGA has been provided notice under the CTN scheme. The protocol has also been submitted to the FDA and part of the CVac IND. The FDA provided comments on the protocol, which we have addressed. There was only one potential "clinical hold" comment where the FDA requested additional specifications for safety lab testing before the first dose of CVac in the protocol. That request has already been met. The CAN-

004 trial, as amended, continues in both countries though we do not necessarily intend to include new patients in second remission from these locations to keep the trial as cost effective as possible.

On another important matter, I should mention that the current civil unrest in several Ukrainian cities has not presented any disruptions to our trial plans as of now. The hospitals, couriers, and labs are working on schedule. In fact, several patients from Part 1 of CAN-004 continue on the trial as normal. Though we hope the situation stabilizes in Ukraine, we realize the situation could indeed deteriorate. As contingency planning, we may potentially add one more European country and we are also reviewing the potential to add in a few Eastern U.S. sites that could deliver cells to our CVac manufacturing facility in Germany efficiently.

Moving on to our plans with the pilot trial in resected pancreatic cancer, the 40-patient, single-arm, pilot trial, protocol number CAN-301. I am pleased to advise that the first patients for this trial can be expected in late July. CAN-301 will include about 20 sites in Europe with Prof. Florian Lordick in Germany as the Coordinating Investigator. While the first expected patients will come slightly behind our intended schedule, the overall recruitment potential for the 40 patients looks to be robust. We anticipate completion of recruitment as we originally planned.

Finally, I would like to give an update on our ongoing manufacturing and product optimization activities. This is a very important part of our development objectives - to bring a cost effective product to the market as well as one that is clinically beneficial. We have made significant progress in two key areas. First is on the shipping stability of mononuclear cells that are collected from each patient to make CVac. We have been able to extend the allowable time window from cell collection to production from 24 to 48 hours, and it appears we may even be able to extend that time period further. This greatly improves the flexibility in our supply chain and yields significant shipping cost reductions. Second, we have made significant progress on testing and developing a surrogate potency test for quality control testing of CVac. We will continue to validate this test in conjunction with clinical trials and, if we are able to validate the utility of the test, it would greatly simplify and reduce the cost of our manufacturing quality control testing.

To summarize, it has been a very busy, and very productive, quarter and we are in a good position to execute on our development plans.

With that, I would like to turn over the call to our CFO, Marc Voigt.

**Marc Voigt – CFO:** Thank you Sharron.

As always, I have a few comments about our finances: In line with Australian regulations, Prima reports financials according to Australian Accounting Standard AASB, which is consistent with IFRS, or the International Financial Reporting Standards. All numbers are in

Australian dollars. Our financial year runs from July 1<sup>st</sup> through June 30<sup>th</sup>. I will be briefly speaking about our Quarterly Report, Appendix 4C, for the third quarter of our financial year 2014. The 4C is primarily a statement of cash flows for the Company and it is not an income statement.

For the quarter ended March 31<sup>st</sup> 2013, the Company reported a net operating cash outflow of A\$ 1.6 million for the quarter. Cash outflow from operations was approximately A\$ 3.58 million. We received operating cash inflows of approximately \$1.98 million in interest, grants, tax refunds, and other income during the quarter. Thus far, for the first three quarters of the financial year 2014, our net operating cash outflow was approximately A\$ 10 million.

We ended the quarter with A\$ 26.74 million in cash, cash equivalents, and term deposits.

Overall, I have been very pleased with our efforts to carefully manage our expenses, especially as we have restructured our clinical plans over the past few months. Through the end of the financial year, we are updating our guidance for the estimated full year loss to approximately A\$ 13 million, which is lower than the A\$ 14 million I had previously guided.

And I will turn the call back over to Matt.

**Matt Lehman – CEO:** Thanks Marc, thanks Sharron, for these updates.

I am pleased that we have been able to get our revised ovarian cancer clinical program up and running on schedule. The next step will be to scale up our clinical trials sites and patient recruitment efforts. I am very excited that we have been able to attract a number of the world's leaders in the ovarian cancer field to support our program and I look forward to updating everyone on a quarterly basis as to our progress.

And of course, we are all looking forward to the final CAN-003 progression free survival data that will be delivered at ASCO here in a few weeks. With that, I'll turn the call back over to the moderator and we'll open the phones for questions.

**Anita Green – Moderator:** Thank you. If you wish to ask a question, please press \*1 on your telephone and wait for your name to be announced. If you wish to cancel your request please press \*2.

**Anita Green – Moderator:**

Your first question comes from David Langsam from Biotech Daily. Please go ahead.

**David Langsam – Biotech Daily:**

Hi, Good morning to those in Australia and Good afternoon to those in the other side. Just a bit of recap question for Matt, firstly congratulation on getting CAN-004's first patient up running the end of last month. I just want to clarify CAN-004 is recalled and CAN-004B or part 2 is recruiting in US, Australia and Europe. That's all for one trial. It seems like you

talked about Europe and separately talked about Australia and US. First question is “Is it the same trial?”

Secondly, a little bit of timelines, how long do you think it will take to get 210 patients and when do you think you will have first line result?

**Matt Lehman – CEO:**

Sure. Let me start perhaps with the first question just to make sure we are really clear. So, CAN-004 if you may remember, that was the trial that has started some time ago, the idea there was we are looking at CVac and the first remission patient population.

That trial was recruiting in Australia and US and a number of European countries. We stopped recruitment of that trial in October last year, and what we have done is we actually revised that trial and as Sharron was pointing, we have actually been separating this trial now into two distinct protocols, so CAN-004 A and CAN-004 B.

**David Langsam – Biotech Daily:**

Hang on. Is the new 210 patient trial for CAN-004 B?

**Matt Lehman – CEO:**

That is correct.

**David Langsam – Biotech Daily:**

Where is CAN-004 B recruiting? In all three jurisdictions?

**Matt Lehman – CEO:**

In that one, we will be going in Europe. As Sharron has mentioned, especially we do have some Ukraine sites, and for some reasons there is a situation deteriorates there, we are looking at potentially some backup solutions either by adding additional larger European countries and or potentially some sites from US to be able to support that.

**David Langsam – Biotech Daily:**

Small follow up question, Matt. Just to clarify, Can-004 B is Europe only at this stage.

**Matt Lehman – CEO:**

Yes Exactly.

**David Langsam – Biotech Daily:**

Thank you very much, that makes sense. And again for the timelines if you are prepared to be that brave.

**Matt Lehman – CEO:**

Right now, we are looking at this taking approximately a year for recruitment. This is something that we will update on a quarterly basis as site scale up patients scale up. And then roughly speaking, based on that kind of timeline, we expect that the time taken to meet

overall survival as a primary end point would probably be approximately towards the end of 2016 of the calendar year. But we are adding in a number of interim data analysis around progression free survival and earlier overall survival tracking how we are going along with that trial. I think as we go on, I would be updating fairly clearly on a quarterly basis when we are expecting the interim data points and interim data analysis conducted and how those would be conducted as we move on. So as I could say, roughly in the top level and we expect the medium overall survival sometime towards the end of 2016.

**David Langsam – Biotech Daily:**

Excellent. Thank you very much for your help.

**Matt Lehman – CEO:**

Sure.

**Anita Green – Moderator:**

Thank you. Once again, if you wish to ask a question now, please press \*1 on your phone.

Your Next question comes from Adam Stoddard from Stoddard Capital. Please go ahead.

**Adam Stoddard – Stoddard Capital:**

Thank you. Matt, just a quick question again to clarify, FDA approval for CAN-004 here in US. [Inaudible]

**Matt Lehman – CEO:**

Sure. The trial CAN-004 B is intended to be recruiting patients in Europe. We have submitted the revised protocol to FDA. This is the trial that will be conducted under FDA IND. I think as Sharron explained protocols in US and the FDA procedures, they do not approve trials per se. What FDA does is they review it and provide us with comments which they actually did. They pointed out what they called Clinical Hold comments. There was only one “clinical hold” comment which was relatively minor and which we will be able to address. In terms of that, the trial is active. The patients on part A of the trial and the sites are continuing on the US. We can consider that CAN-004 part B is now basically proceeding under the IND as well. That is basically how it works. Hope this makes sense.

**Adam Stoddard – Stoddard Capital:**

It does. Thanks for that. Secondly, I saw that Endocyte and Merck partnership had a failure in phase 3 ovarian cancer product. How does it relate to CVac and what is your opinion on that trial in particular?

**Matt Lehman – CEO:**

That is actually very good question. I have been working on it with some advisers as well. I think not everyone is familiar with it but, we are talking about some protocol called Vintafolide. This is a product that was being co-developed by Endocyte in US with Merck. They announced that they had stopped that phase 3 trial. They stopped last week for futility. I

think it is very different kind of product with different mechanism of action. It is targeted molecular therapy. But I do think it is definitely an important lesson we can draw from that experience and some of their trials and data basically how they went from phase 2 to phase 3. We definitely look at some technical specifications on how they were measuring progression free survival on phase 2 program and the understanding of mechanism of actions also understanding of the target patient profile they were looking at. Really importantly, their trial was platinum resistant ovarian cancer. Because these are the patients did not respond platinum ovarian treatment. We are looking at the other side of the ovarian population - the platinum sensitive patient population. I think they were especially looking at patients more difficult to treat in general. I wish I am well and I think it is an interesting approach that they are taking clinical trials and of course we are learning from that as well.

**Adam Stoddard – Stoddard Capital:**

Great! Thank you, Matt for the clarification.

**Matt Lehman – CEO:**

Sure.

**Anita Green - Moderator:** Thank you. That does conclude the question and answer portion of our conference. Ladies and gentlemen, thank you for your participation on the call today. That does conclude our conference. You may all disconnect your lines.

END OF TRANSCRIPT