

ASX ANNOUNCEMENT

Benitec Biopharma Quarterly Report Conference Call Transcript

Sydney Australia, 30 August2017: Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) today lodged its transcript for the conference call taking place at 8.00am AEST on 30 August, 2017.

Good morning everyone.

We have on this call our executive team, Bryan Dulhunty (CFO), Cliff Holloway (CBO/COO), David Suhy (CSO), and Georgina Kilfoil (CCO). David Suhy and I will give the briefing which will take about 15 minutes and we will then take questions.

As a reminder, these calls are in line with our commitment to provide quarterly reporting following our US listing on the NASDAQ in 2015.

Today I will talk about our clinical progress and our orphan and oncology programs being in the clinic next year, as well as provide a brief overview of the financial results for the fiscal year 2017. David Suhy will brief you on our manufacturing capabilities.

We are now at an inflection point as we transition to becoming a clinical stage company once again. We are translating our science into measurable clinical outcomes which we are hopeful will result in significant patient benefit and commercial value for Benitec.

Over the past two years we have used this forum to describe the building of a broad scientific pipeline by harnessing the power of DNA-directed RNA interference (or ddRNAi). Benitec is a primary stakeholder of this proprietary platform technology which has the potential to apply a unique approach to treating human diseases including the opportunity to silence disease causing genes for extended times with a single treatment.

For example, in hepatitis B, we have shown a sustained and significant reduction in viral load, greater than a 4-log reduction, and a further 2 log reduction in s antigen (HbsAg) when a single treatment our ddRNAi therapeutic, BB-103, was combined with standard of care therapy in a preclinical chimeric mouse model. Viral load and s antigen levels are two important biomarkers in determining clinical efficacy.

We are also working with collaborators to identify novel adeno-associated virus (AAV) capsids that may have the potential to transduce tissues like the retina in a way that is both acceptable for patients and commercially valuable.

In relation to transitioning to the clinic, we are initially focused on two programs

The first of these is BB-401, our oncology program. BB-401 is an antisense EGFR asset for the treatment of head and neck squamous cell carcinoma and is scheduled to enter the clinic in a Phase 2 human study in Q1 2018. EGFR is overexpressed in up to 90% of these types of lesions. This compound has performed well in previous early stage clinical studies in patients with refractory forms of the disease to existing therapies.

Manufacturing of the clinical supplies to support the Phase 2 trial is well underway. From the clinical perspective, we have assembled a team of oncology key opinion leaders from the US, UK and Australia to review the prior clinical trial data and assist in designing a robust Phase 2 clinical study to determine the clinical efficacy of BB-401 as a monotherapy. With the final protocol design in hand, we are now turning our attention to clinical site and vendor selection.



It should be noted that the epidermal growth factor receptor (EGFR) target for BB-401 and our follow-on program BB-501, is a key factor in many epithelial malignancies and its activity enhances tumour growth, invasion, and metastasis. Hence, we intend to explore other potential indications, including rare cancers, in future EGFR development programs.

OPMD is the second program that I'd like to focus on, given that entry into the clinic is planned for the second half of 2018. Oculopharyngeal muscular dystrophy is a rare progressive, muscle-wasting disease caused by mutation in the poly(A)-binding protein nuclear 1 gene, that is characterised by eyelid drooping, swallowing difficulties, and proximal limb weakness. There are currently no approved drugs for OPMD. The only treatments offered are palliative in nature – designed to help alleviate the symptoms of the disease. These treatments are a surgical procedure, called a myotomy, in which the throat muscles are physically cut to relieve tension or by having injections of botox into the muscles.

We know the sole genetic basis for this autosomal dominant disease is the expression of a mutant protein. Several months ago, Benitec and its collaborators published preclinical data in the journal Nature Communications, which demonstrated the utility of the "silence and replace" based approach, clearly demonstrating that the treatment was able to correct several phenotypes of the disease including significantly reducing the levels of fibrosis and intranuclear inclusions, the latter of which is the hallmark of the disease, as well as restoring muscle strength back to normal levels in an animal model of the disease.

In recent weeks, we have released news of a significantly improved construct for OPMD, through the development of our innovative single vector system to both silence and replace the OPMD disease-causing gene. We have demonstrated that this single 'silence and replace' vector system (BB-301) can restore muscular function in the preclinical mouse model.

OPMD is a rare orphan indication. This classification provides us with the opportunity to take advantage of regulatory strategies which could accelerate the commercialisation pathway. OPMD is an attractive commercial target for Benitec. Not only are we able to service a high unmet medical need, we are also able to show the benefits of our technology in this type of orphan disease.

Earlier this year, BB-301 was granted orphan designation by the EMA and we anticipate applying for US orphan designation at the appropriate time. Orphan designation both in the US and Europe confers several significant benefits such as market exclusivity, protocol assistance and scientific advice, and waivers or reductions in registration and other fees.

We anticipate meeting later this year with the regulatory agencies in Canada, US as well as in Europe to discuss the planned IND-enabling studies and clinical development plan. To inform our clinical plan, we have engaged some of the world's foremost clinicians and specialist is dysphagia to help develop the clinical platform. In addition, we are actively working with patient advocacy groups so that patients that do have the disease know that they may have the opportunity to participate in the Benitec study.

To summarise, our key message for today's call is that we have two programs which are running to plan and will be in the clinic next year – our Phase 2 oncology program in Q1 2018 and our OPMD program in the second half of the year.

I will now pass over to David Suhy to provide some background on our manufacturing strategy.

Thank you Greg

As you've just heard, Greg has provided an update on the advancement of our pipeline into human clinical studies. Furthermore, we have continuously emphasized the importance of meeting the development timelines that we have communicated to the market.



As a gene therapy-based company, the ddRNAi-based medicines that our scientific team have created are enormously complex drugs. Thus, the design and development of advanced manufacturing solutions early in the product development cycle is crucial to de-risking the future development and maintaining those timelines. Within that context, I wanted to provide some brief colour on our internal efforts to build inhouse manufacturing capabilities and how we are using that same team to solve many of the challenges associated with scalable manufacturing of these complex medicinal products.

Approximately two years ago, recognizing the importance of manufacturing to our long-term success, we started strategically investing into in-house capabilities to be able to produce research grade materials and optimise process development. The initial focus included both the acquisition of capital equipment to physically generate the materials as well as the hiring of highly experienced and talented scientists to produce those materials. The results have been immediately beneficial, allowing us to produce high quality data in a timely manner to support much of the preclinical data that has been presented across our pipeline programs over the last 18 months.

Now, as our attention has been expanding to entry of several programs into the clinic, the focus of the group has likewise expanded into the enhancement of existing methodologies as well as the development of new scalable manufacturing processes for cost-efficient production of large quantities of our drugs. Even products with strong clinical data have failed to make it to market because they cannot be manufactured in adequate quantities and at a reasonable cost. One specific example of how this thinking has influenced our programs is the use of baculovirus based manufacturing schemes to produce the clinical materials for the OPMD program. Production of similar products in baculovirus-based systems showed that this process can be scaled from 1 liter up to several 100 liters or even 1000 liters in a cost efficient manner.

Ultimately, scalable manufacturing and control over long term product supply are inherently linked to product cost, and are critical factors to the commercial viability of our products. To be clear, Benitec will still require the transfer of these processes to third party manufacturers to produce rigorously qualified materials acceptable for use in human clinical studies. Yet as we transfer this knowledge base to our preferred manufacturing vendors we believe this will be a key element to our future success as we engage with commercial partners on the journey to bring our products to patients worldwide.

Greg, back to you

Thank you David

Turning to our fiscal 4th quarter earnings – Benitec's after tax loss for the 2017 financial year was A\$5.7m as compared to A\$24.8m in the prior financial year. The A\$19.1m reduction in the loss this year was primarily as a result of:

- An increase in R&D grant income of A\$6.9m
- Reduction in R&D development costs of A\$6.4m
- Reduction in employee and share based expenses of A\$2.6m

The prior period included:

- IPO costs of A\$1.2m
- A write off of a A\$1.8m clinical trial prepayment

We wrapped up the fiscal year 2017 with cash on hand of A\$17.4 million. This was a decrease of \$0.85m from June 30, 2016 and was represented by:

The raising of A\$7.9m in two placements during the year



• Operating cash outflow of A\$8.3m comprising expenditure of A\$15.9m offset by the government R&D grant received of \$6.2m and other cash receipts of \$1.4m.

We had significant advancements in the last quarter across multiple programs, including.

- OPMD orphan disease program; efficacy with a single vector system
- Ocular program; initiation of *in vivo* proof of concept studies in a non-human primate model
- Infectious disease (hepatitis B) program; pre-IND submission with US Food & Drug Administration for BB-103

Looking forward, the upcoming financial year promises to be a pivotal year for Benitec with our EGFR antisense therapeutic for the treatment of head and neck cancer, moving back into the clinic. Additionally our 'silence and replace' ddRNAi therapeutic for the treatment of OPMD, will be progressing towards the clinic later that year. These milestones further our goal of becoming a multi-product, clinical-stage company by the end of calendar year 2018.

At this time, I will ask the operator for questions.

In closing, I would just like to say that the efforts and strategies of recent years are now delivering with our orphan and ocular programs about to enter the clinic. With funding, our other programs could be clinic ready around the end of 2018.

We are transitioning to becoming a clinical stage company once again and we are hopeful this will result in significant patient benefit and commercial value for Benitec.

Thank you to all our participants today, and especially those shareholders and analysts who provided questions. I would like to thank all our investors for their continued support.

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For further information regarding Benitec and its activities, please contact the persons below, or visit the Benitec website at www.benitec.com

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About Benitec Biopharma Limited:

Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) is a biotechnology company developing innovative therapeutics based on its patented gene-silencing technology called ddRNAi or 'expressed RNAi'. Based in Sydney, Australia with laboratories in Hayward, California (USA), and collaborators and licensees around the world, the company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including hepatitis B, wet age-related macular degeneration and OPMD. Benitec has also licensed ddRNAi to other biopharmaceutical companies for applications including HIV/AIDS, Huntington's Disease, chronic neuropathic pain and retinitis pigmentosa.

Safe Harbor Statement:

This press release contains "forward-looking statements" within the meaning of section 27A of the US Securities Act of 1933 and section 21E of the US Securities Exchange Act of 1934. Any forward-looking statements that may be in the press release are subject to risks and uncertainties relating to the difficulties in Benitec's plans to develop and commercialize its product candidates, the timing of the initiation and completion of preclinical and clinical trials, the timing of patient enrolment and dosing in clinical trials, the timing of expected regulatory filings, the clinical utility and potential attributes and benefits of ddRNAi and Benitec's product candidates, potential future out-licenses and collaborations, the intellectual property position and the ability to procure additional sources of financing. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.