ASX ANNOUNCEMENT

Benitec Biopharma Quarterly Report Conference Call Transcript

Sydney Australia, 30 November 2017: Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) today lodged its transcript for the conference call taking place at 9.00am AEDT on 30 November, 2017.

Good morning everyone.

I am Greg West the CEO of Benitec. Thank you for attending our quarterly briefing. I will give a short overview and will then pass over to David Suhy our CSO to provide a brief update on our science and programs.

As many of you know, Benitec is focused on building a broad scientific pipeline of innovative therapeutics by harnessing the power of our DNA-directed RNA interference technology, known as ddRNAi. This unique platform technology combines gene therapy and gene silencing to change treatment paradigms of human disease. We are translating our science into measurable clinical outcomes which, if successful in the clinic, will have the potential to improve treatment outcomes as well a provide significant commercial value for Benitec.

We have a robust pipeline with assets in oncology, orphan genetic disorders, retinal disorders and infectious disease. We anticipate that two of these assets will be in the clinic by the end of 2018.

The Benitec you see today is very different to the Benitec of two years ago.

- Benitec has transitioned into a product development company with a pipeline focused on areas which, if successful in the clinic, will provide a high probability of return on investment and commercial success.
- We have an oncology asset which will be entering a Phase 2 clinical trial in 1Q 2018.
- In addition, we have a unique 'silence and replace' therapeutic designed to treat an orphan disease called oculopharyngeal muscular dystrophy, or OPMD, that will be entering the clinic at the end of 2018.
- Lastly, we have other earlier stage programs targeting retinal disorders and infectious disease
- Our dual listing on both the ASX (2002) and NASDAQ (August 2015) provide strong capital markets access. Benitec has raised US$40m since 2014 and has a US shelf registration that was filed in June of this year.
- We have strong in-house capabilities with operations in both Sydney Australia and Hayward California including a scientific staff of 13 PhDs with deep gene therapy expertise. This includes in-house manufacturing expertise for process optimization and scalability.

As a company and executive team, we have communicated what we are going to do and we have delivered on our promises. This has led us to be where we are today – at a critical inflection point as we transition to becoming a clinical stage company again.

Over recent years, since I took over as CEO, we have been through a process of renewal both at the executive level and also with our Board. We have also changed our business so our pipeline is now focused on four key indications to drive shareholder value.

Turning to business development, I know some shareholders have raised comments regarding ongoing business development now that Cliff Holloway has taken a CEO role with a listed biotechnology company in the UK. We certainly wish him the best.

When it comes to business development, each of the pipeline streams requires a different plan of attack. In that context, for hepatitis B, we have spoken to the major companies in North America and Europe and many at the next tier as well. Prior to Cliff leaving we have connected with a number of deal doing intermediaries who specialize in the hepatitis B area and bridge between small biotech and big pharma. They have confirmed the strategy adopted to date and we will use their services to work with us to transact our HBV asset.

In relation to our ocular program, we have similarly connected with pharmas who would have appetite for our technology and we will be using specialty deal markers in the ocular area to create opportunities to transact as the asset value emerges from our current R&D programs.

The oncology asset is in Phase 2 development moving to a second generation ddRNAi and as results emerge from our scientific work we will consider our business development approach on this asset.

We intend to develop and commercialize OPMD ourselves. We may contemplate a strategy of partnering once we have initial data with BB-301 in a clinical setting, an inflection point which positions the asset with far greater value than the current stage.

Turning to our earnings for the first fiscal quarter of 2018 – Benitec's after tax loss for the September 2017 quarter was A$2.9m compared to a profit of A$0.8m in the September 2016 quarter. The principal reason for the increase in net loss of A$3.6m is that in the September 2016 quarter, federal government grant of A$4.9m was recognised as revenue, on a cash basis. The grant related to the 12-month period ended 30 June 2016. Since March 2017, the Company has recognised R&D Grant revenue on a quarterly accrual basis, in accordance with revised accounting standards.

At the end of the September 2017 quarter, we had cash on hand of A$14.7m, a decrease of $2.7m from the June 2017 quarter.

As we near the end of 2017 it is useful to reflect on some of the major achievements of the past year

- We completed the investment from Nant Capital and brought in a Phase 2 oncology clinical asset (BB-401)
- Preclinical OPMD data with a dual vector system was published in Nature Communications using a unique 'silence and replace' therapeutic modality. This was followed by pre-clinical efficacy data presented that showed the utility of a single vector system which is the therapeutic construct we will be progressing to the clinic.
- The European Union granted orphan drug designation for our OPMD program and we have also now submitted an application to the U.S. Food & Drug Administration seeking orphan drug designation for BB-301.
- We completed successful pre-IND and scientific advice meetings with the U.S. FDA, Health Canada and several European agencies for our OPMD program.
- We released pivotal preclinical efficacy data for our hepatitis B program.
- A pre-IND meeting was held with the US FDA and informed us of a clear and expeditious path into the clinic for our hepatitis B asset
- We received Australian R&D grant income of A$10.5m for the 2016-2017 fiscal year

I will now pass over to David to provide more colour around our programs

Oncology

BB-401 is a recombinant DNA plasmid construct that produces an antisense RNA molecule with specificity against the epidermal growth factor receptor (EGFR) and is currently under development for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC) in patients who have failed all available standard therapies. EGFR has been identified as a protein that can have oncogenic properties, and thus by inhibiting the expression of this molecule, we hope to be able to control disease progression. As a reminder, BB-401 has performed quite well in two early stage clinical studies.

There are a number of parallel activities that are in high gear which will able us to initiate a phase II study for the BB-401 program. The intention is to run the clinical study in both Australia as well as Russia using up to 60 patients. The trial is being run with a clinical protocol designed to examine the impact of up to 8 injections of BB-401 into a lesion associated with head and neck squamous cell carcinoma. In addition to the impact on the injected lesion, the trial is meant to monitor progression free survival, the durability of response as well as monitor biomarkers associated the treatment including the persistence of BB-401 and expression of the antisense RNA transgene.

Manufacturing of the clinical product is now complete and has passed all of the release tests for human clinical use, except one ongoing assay which takes an extended amount of time to finish. As Greg just mentioned, this is a program in which we intend to be dosing patients in Q1 of 2018.

Finally, it is worth mentioning that in addition to HNSCC, EGFR overexpression has been associated with a number of cancers, including epithelial tumors of the head and neck, squamous cell cancers of the lungs, anal cancers, and glioblastoma. As such, Benitec is exploring other potential clinical indications for anti-EGFR strategies, including rare cancers.

OPMD

One of the most exciting developments related to the progression of the BB-301 program is the completion of several regulatory meetings with agencies in the United States, Canada and several within Europe. There may also be additional regulatory meetings planned in 2018 for additional countries. The purpose of these meetings was to discuss the regulatory development pathway for BB-301 as a treatment for OPMD and to ensure Benitec's proposed development program which includes the existing data, manufacturing and the clinical study design addressed the regulatory expectations of these agencies. For several of the agencies, it was their first exposure to a single vector "silence and replace" based gene therapy product which generated a substantial amount of interest.

The next steps in the development path includes performing the required safety studies in large animal models which are needed to be able to proceed with BB-301 entry into the clinic. These are a series of experiments to ensure that the procedures we use to dose patients as well as the doses of drugs that we intend to use do not cause any obvious problems. In addition, remaining items include the manufacture of the clinical lots of BB-301 that will be dosed into the human subjects. As mentioned in the last quarterly call, the transfer of the production protocols and optimization of the processes related to the manufacturing of BB-301 are well underway at Benitec's contract manufacturing organization. The baculovirus-based production methodologies have yielded a product that has performed strongly in the A17 mouse model of efficacy.

Finally, it is important to note we are striving to remain closely connected to patient advocacy groups. As one example, we recently presented at a conference in which an OPMD patient and his wife appeared in the audience and had an opportunity to learn about how we are harnessing ddRNAi to treat this disease. Likewise, we have recently attended an event with a large number of OPMD patients and their families where we had the opportunity to talk about the development pathway of BB-301. The meetings that we have had with these gracious individuals has been inspiring. Each has been eager to share the stories of their disease, as well as the stories of the generations that proceeded them. Importantly, they all universally expressed enthusiasm that our efforts may provide hope for themselves as well as their children. It was truly a humbling experience to be able to put a human face to the disease and provides an even stronger motivation to move expeditiously towards the clinic.

Retinal disease

Benitec continues development of its program to treat retinal diseases with an initial program designed to treat subjects impacted by the wet form of age-related macular degeneration (AMD), a disease caused by the growth of new blood vessels into ocular tissues. Designated as BB-201 and intended as a product administered once, this construct expresses three independent shRNA designed to silence VEGF-a, VEGF-b and PlGF, three well validated targets known to contribute to the disease and secreted from the RPE cells deep within the retina.

As previously discussed, Benitec has been working with collaborators to identify novel AAV capsids that have shown enhanced transduction of retina cell layers following the commercially friendly route of intravitreal injection, a technique currently used to deliver the standard of care drugs most commonly used to treat wet AMD.

We have recently completed the in-life portion of an in vivo proof of concept study in a non-human primate model. In this study, we examined the ability of BB-201 to prevent vascular leakage from new blood vessel formation that occurs following the treatment of the retina with several laser burns. Although the molecular analyses of all of the retinal tissues have not been completed, it is clear from the initial in-life portion of the data, that additional work on BB-201 will be required if we are to continue the development of the AMD program. The additional work will help us determine the distribution of BB-201 using the new capsids and the relative expression levels of each of the shRNAs.

At Benitec, we strive to be recognized as trailblazers in the gene therapy community by developing innovative approaches such as single vector “silence and replace” methodologies to treat genetic diseases or helping discover the next generation delivery technologies that will transform the way that gene therapy products can be administered. In doing so, we believe that we are creating long term inherent value for the business and our shareholders.

Greg, back to you

Thank you David

Benitec is a changed business. We have revised our pipeline and renewed our executive and Board teams. We have established a strategic relationship with a quality partner in Nant Capital. We have a solid thoughtful business approach and targeted scientific outcomes. We are delivering on what we said we would do.

The news flow over the next year is around moving into the clinic in oncology and OPMD, with other programs potentially clinic ready shortly thereafter.

We strongly believe that we are uniquely positioned to develop therapeutic compounds with novel product profiles coupled with the potential of superior clinical activity in each of these disease areas. We believe that it is going to be the initiation of the two clinical studies that will be the major catalysts for value creation in 2018. A phase II study is slated to begin in Q1 for the use of BB-401 to treat HNSCC. Later in the year we anticipate being ready to enroll the first patient in the first in man OPMD study. These milestones speak to our strategy of becoming a multi-product, clinical-stage company and represent an opportunity for significant shareholder value.

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.

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.

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

Australia Investor Relations

Market Eye
Orla Keegan
Director
Tel: +61 (2) 8097 1201
Email: orla.keegan@marketeye.com.au

United States Investor Relations

M Group Strategic Communications
Jay Morakis
Managing Director
Tel: +1 212.266.0191
Email: jmorakis@MGroupSC.com

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 OPMD, head & neck squamous cell carcinoma, retinal based diseases such as wet age-related macular degeneration, and hepatitis B. Benitec has also licensed ddRNAi to other biopharmaceutical companies for applications including HIV/AIDS, Huntington's Disease, chronic neuropathic pain, cancer immunotherapy 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 this ASX/Nasdaq announcement are subject to risks and uncertainties relating to the difficulties in Benitec's plans to develop and commercialise 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.