

## **ASX/NASDAQ ANNOUNCEMENT**

### **Chairman and CEO Address at the Annual General Meeting Held on Wednesday 8 November 2017**

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**Sydney Australia, 8 November 2017**

#### **Chairman's address**

Good morning everyone. My name is Jerel Banks and I am the Chairman of Benitec. Thank you for joining us today for our Annual General Meeting.

As many of you know, I am also the Chief Investment Officer of NantVentures, which is the largest shareholder in Benitec.

At the last Annual General Meeting, which was shortly after Nant's investment in Benitec had been announced, I addressed the audience with my views of the company and those views continue to apply. What I see is that the team at Benitec has made strong progress in an important area of scientific research and development that has the potential to improve the standards of care across many clinical indications for which the unmet need remains significant. The Nant investment in Benitec demonstrates our long-term interest and confidence in the Benitec technology and vision for the business as it develops innovative single administration treatments for human disease using gene therapy.

Before I hand off to our CEO, Greg West, to deliver a review of the 2017 financial year, I would like to make some comments on behalf of the Board that speak to the vision and the transformation you have seen in Benitec over recent years.

We have seen Benitec transition 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. Greg and his team have communicated what they are going to do and have delivered on their promises. This has led Benitec to where it is today, at a momentous inflection point as it transitions to becoming a clinical stage company.

Your Board of Directors has strongly endorsed this vision and strategy and, on behalf of the Board, I would like to thank Greg, our executive team and all our staff for their commitment and hard work in getting us to where the company is today.

I would also like to thank my fellow directors, our partners and you, our shareholders, for your support.

I would now like to hand over to Greg to speak to the recent activities and achievements of Benitec over the past year, as well as the outlook for financial year 2018 (FY18).

#### **CEO address**

As Jerel has noted, we have been focused on building a broad scientific pipeline of innovative therapeutics by harnessing the power of our DNA-directed RNA interference technology. 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 result in significant patient benefit and commercial value for Benitec.

Reflecting on 2017, some of our key achievements that have defined our path to value creation are as follows:

- We completed the second tranche of an investment with Nant Capital and brought in a Phase 2 oncology clinical asset. Importantly, this asset is scheduled for return to the clinic in Q1 2018
- The European Union granted orphan drug designation for our program in oculopharyngeal muscular dystrophy (or OPMD)
- Initial OPMD 'silence and replace' preclinical data was published in Nature Communications
- Pivotal preclinical efficacy data was released with BB-103 in hepatitis B
- A Pre-IND meeting was held with the US FDA and informed us of a clear and expeditious path to the clinic for BB-103, our hepatitis B asset
- We received Australian R&D grant income of A\$10.5m for the 2016-2017 fiscal year

### ***Oncology***

One of our leading programs, BB-401, the antisense EGFR asset for head and neck squamous cell carcinoma, is currently scheduled to enter the clinic in a Phase 2 human study in the first quarter of calendar year 2018.

EGFR is overexpressed in up to 90% of these types of lesions and BB-401 has performed well in previous early stage clinical studies in patients with forms of the disease that was refractory to existing therapies. We have assembled a team of oncology key opinion leaders from the US, UK and Australia to assist in designing a robust Phase 2 clinical study.

Manufacturing of the clinical supplies to support this study is complete and we are working with our partners to select clinical sites and prepare the regulatory submissions.

### ***Orphan***

OPMD 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.

Earlier in the year, we and our collaborators published preclinical data in the scientific journal Nature Communications, that highlighted the utility of the 'silence and replace' based approach. It clearly demonstrated that the treatment could correct several phenotypes of the disease including significantly reducing the levels of fibrosis and intranuclear inclusions, the latter of which are the hallmark of the disease. It also showed muscle strength restoring back to normal levels in an animal model of the disease.

More recently, we 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 (termed BB-301) can restore muscular function in a preclinical mouse model that replicates this debilitating disease.

We are presently meeting with the regulatory agencies in the US and Canada, as well as in various sites in Europe to discuss the proposed IND-enabling studies and clinical development plan. In fact, the reason why our Chief Scientific Officer, David Suhy and our Chief Clinical Officer, Georgina Kilfoil are attending this meeting by phone is that they are working through a schedule of back-to-back regulatory meetings with these agencies.

We have engaged some of the world's foremost clinicians in OPMD as well as specialists in dysphagia to help develop the clinical platform and to advance BB-301 into the clinic as expeditiously as possible.

Looking forward, the upcoming financial year promises to be a pivotal year for Benitec with BB-401, our EGFR antisense therapeutic for the treatment of head and neck cancer, moving back into the clinic. Additionally, BB-301, our 'silence and replace' ddRNAi therapeutic for the treatment of OPMD, is progressing towards the clinic.

These milestones further our goal of becoming a multi-product, clinical-stage company. Both of these programs represent an opportunity for significant commercial and shareholder value.

I would like to take this opportunity to thank our dedicated team. We remain committed to developing our ddRNAi technology, a novel combination of gene therapy and gene silencing, to change treatment paradigms of human disease. We look forward to an exciting year ahead and to becoming a multi-stage clinical company.

I will now hand back to Jerel to commence the formal business of the Annual General Meeting.

For further information regarding Benitec and its activities, please contact the persons below, or visit the Benitec website at [www.benitec.com](http://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 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 the press release 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.



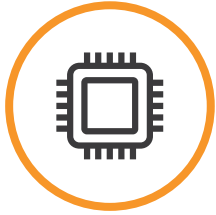
NASDAQ: BNTC | ASX: BLT

# PATH TO VALUE CREATION

November 2017

# BUSINESS OVERVIEW

A multi-product clinical stage company in 2018



## Proven Technology

Validated technology with two clinical assets by the end of 2018



## Robust Pipeline

Assets in oncology, orphan genetic disorders, retinal disease, and infectious disease



## Valuable Products

Human therapeutic products for commercialization, partnering, and collaborations

Benitec has created a novel combination of gene therapy and gene silencing to change treatment paradigms of human disease



# RECENT ACHIEVEMENTS

And path to value creation

## Achievements

- ✓ Nant Capital makes strategic investment in Benitec and brings in Phase II oncology asset
- ✓ EU orphan drug designation for oculopharyngeal muscular dystrophy (OPMD)
- ✓ Nature Communications publication of initial 'silence and replace' preclinical data (OPMD)
- ✓ Proof of concept for ocular delivery of gene therapy
- ✓ Pre-IND meeting with US FDA informed a clear and expeditious path to the clinic for BB-103
- ✓ Australian R&D grant income of A\$10.5m for 2016-2017 fiscal year

# PROGRAM SUMMARY



## BB-401/BB-501: Oncology (HNSCC)

- EGFR antisense asset BB-401 planned to enter the clinic in 1Q18
- Enhanced follow-on therapeutic BB-501 based on ddRNAi
- Clinical studies planned in recurrent or metastatic head and neck squamous cell carcinoma



## BB-301: Orphan disease (OPMD)

- Takes advantage of unique 'silence and replace' mechanism
- Strong preclinical 'silence and replace' efficacy shown with a single vector system



## BB-201: Retinal disease (AMD)

- Identified novel viral capsids for delivery to retinal cells via intravitreal injection
- Ongoing PoC in non human primates using laser induced model of neovascularization – data 4Q17
- Potential use of delivery platform to treat other retinal diseases



## BB-103: Infectious disease (HBV)

- Preclinical POC showed significant reduction in viral load (>4 log) and HbsAg (>2 log) combined with SOC
- Pre-IND meeting in April 2017 informed direct path to clinic entry
- Seeking partnerships to move the program into the clinic

# VALUE CREATION

Two programs in the clinic

## Value Creation



Near term value inflection points as programs move into the clinic and clinic-ready in 2018



Multi stage clinical company at the end of 2018



Flexibility of ddRNAi platform can accelerate clinical and shareholder value with the ability to move proven ddRNAi therapeutics into additional rare diseases



# COMPANY HIGHLIGHTS



## Programs advancing to clinic

Phase II ready EGFR-targeted gene silencing therapeutic achieved POC in head and neck cancer entering confirmatory Phase II trial in Q1 2018

Unique 'silence and replace' therapeutic designed to treat orphan disease oculopharyngeal muscular dystrophy progressing towards the clinic

Other programs targeting retinal disorders and infectious disease expected to be clinic-ready late 2018



## Capital markets access

Listed on ASX (2002) and NASDAQ (2015)

US\$40M capital raised since 2014

US shelf registration June 2017



## Strong in-house capabilities

23 staff with scientific operations in Hayward CA, including 13 PhDs with deep gene therapy expertise

In-house manufacturing expertise for process optimization and scalability

Extensive commercial and drug development expertise

# SAFE HARBOR STATEMENT

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