

# **ASX/NASDAQ ANNOUNCEMENT**

# Benitec Biopharma reports financial results for the 2018 fiscal third quarter and provides operational update

**Sydney, Australia, 31 May 2018:** Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) ("Benitec" or "the Company"), a biotechnology company developing innovative therapeutics based on a combination of gene therapy with its patented gene-silencing technology called ddRNAi or 'expressed RNAi', today reported its consolidated financial results for the 2018 fiscal third quarter to 31 March 2018 (3Q FY18), and highlighted recent progress advancing its pipeline.

## March 2018 Quarter (3Q FY18) Highlights

- Advancements of pipeline programs included:
  - Oculopharyngeal muscular dystrophy (OPMD); in January 2018, the United States Food
    & Drug Administration (U.S. FDA) granted orphan drug designation to BB-301.
  - o OPMD; in February 2018, Benitec completed a positive scientific advice meeting with the French regulatory agency (ANSM).
  - OPMD; in March 2018, Benitec successfully produced high titer and highly active supplies of BB-301 at a 50L scale. This material is being used in the toxicology studies. Ultimately, manufacturing runs up to 250 liters will be used to produce BB-301 clinical supplies.
  - OPMD; in May 2018, after the quarter close, Benitec held a face-to-face meeting with its world class group of leaders in swallowing and the treatment of OPMD to finalise the plans for the first clinical study with BB-301.
  - Head and neck squamous cell carcinoma (HNSCC); in March 2018 the Phase 2 study with BB-401 was approved to start in Australia. Subsequent to quarter close, Ministry of Health approval was received in Russia and Benitec anticipates having Russian sites active in the upcoming quarter.
- Cash on hand of A\$10.5 million at 31 March 2018, with A\$4.1 million of R&D grant cash received in January 2018.
- Subsequent to the quarter close, on the 4 May 2018, the Company placed approximately A\$2.6 million with Highbridge Capital Management LLC.
- Subsequent to the quarter close, Benitec raised A\$6.2 million from an entitlement offer which closed on the 28 May 2018.

Commenting on recent pipeline progress, Chief Executive Officer Greg West said: "I am pleased with the progress we continue to make on both our oncology and OPMD programs. Our first site is now active for the Phase 2 study of BB-401 as a treatment for head and neck squamous cell carcinoma and we look forward to hopefully treating our first patients soon. The OPMD program continues to make steady progress towards the clinic. The feedback received from the regulatory agencies and



our Key Opinion Leaders is validation of the importance of, not only this program, but also the 'silence and replace' approach to treating other orphan diseases. We look forward to continuing to share positive news on our progress."

#### March 2018 Quarter (3Q FY18) Financial Results

Benitec reported a net loss of A\$8.6m for the nine month to 31 March 2018 (3Q FY18) compared to a loss of A\$3.1m in the March 2017 quarter (3Q FY17). The principal reason for the increase in net loss of A\$5.5m is due to a reduction in Research and Development grant income of \$6.3m offset by a decrease in R&D spend of A\$0.4m and other costs of A\$0.4m.

At the end of the March 2018 quarter, Benitec had cash on hand of A\$10.5m, a decrease of \$6.8m from the June 2017 quarter. This decrease represents operating cash outflow of \$11.2m offset by income of \$0.39m, purchase of plant and equipment of \$0.08m, a foreign exchange loss of \$0.05m and A\$4.1 million of R&D grant cash received in January 2018.

### March 2018 Quarter (3Q FY18) Operational Update

## Orphan Disease (OPMD) Program: BB-301

Benitec continues advancement of an innovative single vector system with the capability to both 'silence and replace' disease causing genes. In addition to using RNA interference to 'silence' the mutant PABPN1 gene expression that causes OPMD, BB-301 simultaneously introduces a normal copy of the same gene thus providing the potential to restore normal function to the treated tissues and in the process, improve treatment outcomes. The Company considers the 'silence and replace' modality a significant advancement not only for the OPMD program, but also in the potential treatment of other orphan diseases:

- Benitec has now initiated the IND-enabling toxicology studies with BB-301. These studies are being conducted in sheep, an animal model selected because the weight and size of the key muscles in the upper digestive system are consistent with human subjects. Given the complexity of the intramuscular route of administration in the sheep and input from the regulatory agencies, the size of the toxicology studies has been increased resulting in slightly slower timelines. It is now anticipated that the regulatory filing to support the Phase 1/2 clinical study with BB-301 will be made in the 1<sup>st</sup> quarter calendar year 2019.
- High titer and highly active supplies of BB-301 have now been produced at a 50-liter scale. These supplies will be used in the ongoing toxicology studies. Benitec is now focused on producing supplies at a 250-liter scale which will support the clinical program.
- The Company completed a successful scientific advice meeting with the French regulatory agency (ANSM). The input from this meeting has been incorporated into the BB-301 clinical and regulatory strategies.
- Benitec received orphan drug designation from the U.S. FDA for BB-301 as a treatment of OPMD.
- The Company has gathered a world class group of leaders in swallowing and the treatment of OPMD who will be assisting in designing the first clinical study. In May 2018, after the quarter



close, Benitec held a face-to-face meeting with these experts to finalise the plans for the first clinical study with BB-301.

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

- A Phase 2 human clinical trial for BB-401, a DNA construct that expresses an antisense RNA directed against the epidermal growth factor receptor (EGFR), for the treatment of patients with HNSCC, is now active (clinicaltrials.gov identifier: NCT03433027).
- In March 2018, regulatory and ethics committee approval for the first sites in Australia was received. Russian Ministry of Health regulatory approval for the Phase 2 study was received in May 2018, after the quarter close.
- Pre-clinical testing in mouse xenograft models is ongoing for BB-501, the follow-on anti-EGFR based ddRNAi construct, to treat head and neck squamous cell carcinoma.
- As EGFR is a key factor in many epithelial malignancies and its activity enhances tumor growth, invasion, and metastasis, Benitec intends to explore other potential clinical indications, including rare cancers.

## **Conference Call Information**

Benitec management will provide an operational update to discuss the 3Q FY18 results and expectations for the future, via conference call on Friday, 1 June 2018 at 7:00am AEST (Australia)/ Thursday, 31 May 2018 at 5:00pm EDT.

To access the call, please dial 1 800-908-299 (Australia) or 1 855-624-0077 (U.S.) five minutes prior to the start time and refer to conference ID 987652. An archive of the webcast will remain available on Benitec's website for 90 days beginning at approximately 11:30am AEST on 1 June 2018.



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.

#### 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.