# ASX/NASDAQ ANNOUNCEMENT

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

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**Sydney, Australia, 22 February 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 second quarter to 31 December 2017 (2Q FY18), and highlighted recent progress in advancing its pipeline.

**December 2017 Quarter (2Q FY18) Highlights**

- Advancements of pipeline programs included:
    - Oculopharyngeal muscular dystrophy (OPMD); in January 2018, subsequent to the quarter end, the United States Food & Drug Administration (U.S. FDA) granted orphan drug designation to BB-301.
    - OPMD; completed positive pre-IND and scientific advice meetings with the FDA, Health Canada and several European agencies.
    - OPMD; the processes related to cost efficient manufacturing of BB-301 using baculovirus-based technologies to support the first in man studies later in 2018 is currently at the 50-liter scale. Ultimately, manufacturing runs up to 250 liters will be used to produce BB-301 clinical supplies.
    - Head and neck squamous cell carcinoma (HNSCC); completion of initial regulatory/ethics committee submissions to support the upcoming Phase 2 study with BB-401.
- Cash on hand of A$10.3 million at 31 December 2017, with A$4.1 million of R&D grant cash received in January 2018.
- Loss for the six months to 31 December 2017 was A$5.8 million as compared to a loss of A$3.0 million in the previous corresponding period.

Commenting on recent pipeline progress, Chief Executive Officer Greg West said: "I am pleased that we continue to advance both our oncology and OPMD programs towards the clinic. Receiving orphan drug designation for BB-301 from the FDA is yet another validation of the importance of the OPMD program. We look forward to continuing to share positive news as we execute on our goal of becoming a multi-product, clinical-stage company by the end of calendar year 2018."

**December 2017 Quarter (2Q FY18) Financial Results**

Benitec reported a net loss of A$5.8m for the December 2017 quarter (2Q FY18) compared to a loss of A$3.0m in the December 2016 quarter (2Q FY17). The principal reason for the increase in net loss of A$2.8m is due to a reduction in Research and Development grant income of $3.8m offset by a decrease in R&D spend of A$0.7m and other costs of A$0.3m.

At the end of the December 2017 quarter, Benitec had cash on hand of A$10.3m, a decrease of $7.1m from the June 2017 quarter. This decrease represents operating cash outflow of $7.2m offset by income of $0.35m, purchase of plant and equipment of $0.08m and a foreign exchange loss of $0.05m. The Company received A$4.1 million of R&D grant cash in January 2018.

**December 2017 Quarter (2Q FY18) Operational Update**

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

- Regulatory filing planned for 4th quarter of calendar year 2018. Assuming approval on a normal time-frame, Benitec should be starting a Phase 1/2 clinical study with BB-301 by the end of calendar year 2018.
- 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.
- A single gene therapy product, versus an equivalent system with two or more vectors, vastly simplifies the manufacturing and regulatory processes and reduces the complexity of the clinical strategy for BB-301.
- Manufacturing methodologies to produce BB-301 are currently being run at batch sizes of 50 liters. Work continues to develop optimize manufacturing into a process that will produce materials at a scale of 250 liters.
- Benitec received orphan drug designation from the U.S. FDA for BB-301 as a treatment of OPMD.
- In this quarter Benitec completed successful pre-IND and scientific advice meetings with the U.S. FDA, Health Canada and several European agencies. Input from these meetings has been incorporated into the BB-301 clinical and regulatory strategies.
- Benitec 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.
- Benitec 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.

**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 planned to start in the first quarter calendar year 2018 (clinicaltrials.gov identifier: NCT03433027).
- Benitec is on track with the start-up activities to support the Phase 2 study for BB-401. Regulatory and ethics committee submissions have been completed and the first approval is expected in March.
- 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.

**Upcoming Presentations**

- Benitec will present at the 30th Annual Roth Conference, which is being held 11-13 March 2018 at Dana Point, CA.

**Conference Call Information**

Benitec management will provide an operational update to discuss the 2Q FY18 results and expectations for the future, via conference call on Friday, 23 February 2018 at 9:00am AEDT / Thursday, 22 February at 5:00pm EST. 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 355790. An archive of the webcast will remain available on Benitec's website for 90 days beginning at approximately 11:30am AEDT on 23 February 2018.

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 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.