

Benitec Biopharma Ltd

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#### **ASX ANNOUNCEMENT**

#### BENITEC ROADSHOW INVESTOR PRESENTATION

**Sydney, 11 June 2014:** Benitec Biopharma Limited (ASX: BLT) (OTC: BTEBY) is pleased to release a copy of the presentation that Dr Peter French, CEO and Managing Director, will be delivering to investors during a non-deal roadshow in the USA during June.

The presentation highlights Benitec's progress on the company's ddRNAi programs and provides an update on the establishment of the California laboratory

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

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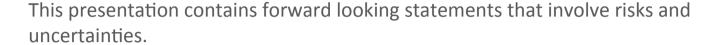
**About Benitec Biopharma Limited:** Benitec Biopharma Limited is an ASX-listed biotechnology company (ASX Code: BLT) (OTC Code: BTEBY) based in Sydney, Australia. The company has a pipeline of in-house and partnered therapeutic programs based on its patented gene-silencing technology, ddRNAi. Benitec is developing treatments for chronic and life-threatening human conditions such as Hepatitis C, Hepatitis B, wet age-related macular degeneration, cancer-associated pain, drug resistant lung cancer and oculopharyngeal muscular dystrophy based on this technology. In addition, Benitec has licensed ddRNAi technology to other biopharmaceutical companies who are progressing their programs towards the clinic for applications including HIV/AIDS, retinitis pigmentosa and Huntington's disease. For more information on Benitec refer to the Company's website at <a href="https://www.benitec.com">www.benitec.com</a>.







### Forward looking statement



Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Benitec Biopharma can give no assurance that these expectations will prove to be correct.

Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, risks associated with patent protection, future capital needs or other general risks or factors.

This document does not constitute an offer, solicitation or recommendation in relation to the subscription, purchase or sale of securities in any jurisdiction. Neither this presentation nor anything in it will form any part of any contract for the acquisition of securities.

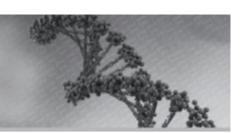




Key Financials	ASX:BLT
	ОТС: ВТЕВУ
Share Price as at close of trade 3 June 2014:	AUD \$1.10
Market Capitalisation (fully diluted) as at 3 June 2014:	AUD \$126.4M
Issued Securities as at 29 April 2014:	
Ordinary shares	114,895,525
Options	23,140,177
Cash balance at 31 March 2014:	AUD \$18.4 M



### Access to Benitec Biopharma via U.S. OTC Market



#### ADR Benefits to U.S. Investors:

- ADRs give direct access to our listed equity capital base allowing participation in cross-border market liquidity
- Company disclosure via OTC website
- ADRs are cost-effective
- ADRs are convenient to transact and own
- Quoted in U.S. dollars
- Settle via standard U.S securities settlement process
- Program is administered by a market leading global depositary

Benitec Biopharma ADR trading info:

Symbol BTEBY

CUSIP 082053208

Ratio 1 ADR : 5 ORDs

**Country** Australia

Effective Date
May 30, 2014

**Underlying SEDOL** 6710507

Underlying ISIN AU000000BLT8

Depositary BNY Mellon

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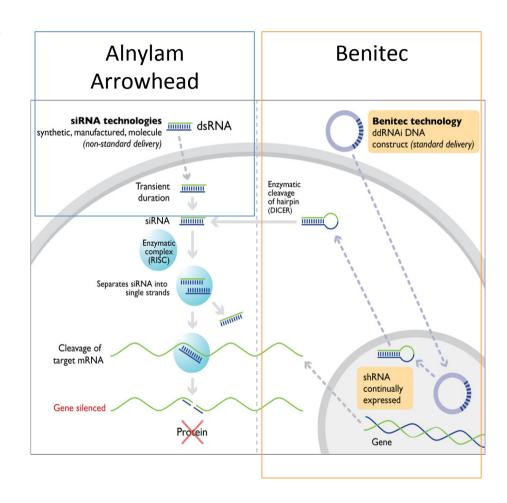
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# ddRNAi Technology The next revolution in gene silencing

- A specific and long lasting method for turning off disease-associated genes
- ddRNAi technology utilises the power and specificity of RNAi while avoiding many of its problems
  - Specific delivery to target cells
  - Fewer side effects
  - <u>Lasting benefits</u> –dsRNA generated continuously for the life of the cell
  - Multiple therapy in a single molecule can be engineered to silence a specific gene, multiple sites on a gene or multiple genes
- Protected by a dominant, global patent estate - over 100 patents covering ddRNAi and specific disease targets







Focus	Indication	Partners / Collaborators	Discovery	Pre-clinical	Clinical
Infectious Disease	Hepatitis C				
	Hepatitis B	Biomics Biotechnology (JV)			
Cancer	Non Small Cell* Lung Cancer	University of New South Wales (RC)			
	Cancer Associated Pain	Stanford University (RC)			
Ocular Disease	AMD**				
Genetic Disease	OPMD***	Royal Holloway London University (RC)			

RC = research collaboration JV = joint venture





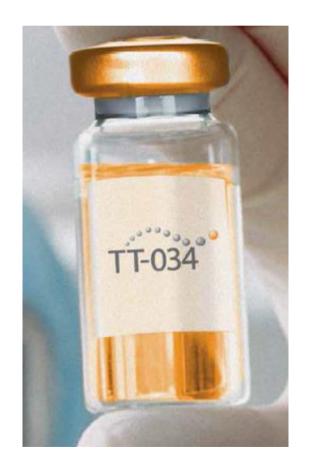
Focus	Indication	Partners/Collaborators	Discovery	Pre-clinical	Clinical
Infectious Disease	HIV/AIDS	Licensed to Calimmune			
Cancer	Cancer Vaccines	Licensed to Regen BioPharma			
Ocular Disease	Retinitis Pigmentosa	Licensed to Genable			
Genetic Disease	Huntington's Disease	Licensed to uniQure	_		



- > TT-034 is an RNAi therapeutic that is intended as a "one-shot-cure"
- ➤ Goal is to achieve complete and sustained elimination of virus with a single infusion
- > US-based open-label dose-escalation Phase I/IIa trial underway
  - Regulatory activity:
    - ✓ Patient dosing commenced May 29, 2014
    - ✓ FDA released IND January 12, 2014 within 30 days of submission with no major questions
    - ✓ Protocol reviewed and approved by NIH RAC June 2013 with unanimous panel support

#### > Trial sites

- Duke Clinical Research Unit, North Carolina currently dosing & continuing to screen additional patients
- University of California, San Diego finalising agreement





Cohort	Dose (vg/kg)	Dose escalation step (log 10)	Total No subjects	Dosing scheme for subjects	Observation period per subject and between cohorts before dose escalation
1	$4.00 \times 10^{10}$	Starting dose	2	Sequential (1+1)	6 week
2	1.25 × 10 <sup>11</sup>	0.5	3	Sequential and parallel (1+2)	6 week
3	4.00 × 10 <sup>11</sup>	0.5	3	Sequential and parallel (1+2)	6 week
4	1.25 × 10 <sup>12</sup>	0.5	3	Sequential and parallel (1+2)	10 weeks
5	4.00 × 10 <sup>12</sup>	0.5	3	Sequential and parallel (1+2)	10 weeks

- DSMB review after first patient in each cohort and between cohorts
- Extensive safety monitoring during 24 weeks observation





- Expect interim safety data 2H 2014
- Expect efficacy data 1H 2015 positive results should be a significant value inflection milestone for Benitec
- Clinical demonstration of a "game changer" for treatment of HCV As a "single shot cure," TT-034 would compete with small molecule cocktails:
  - Compliance, side effect profile, efficacy, cost effectiveness
- Provides a validation of Benitec's other pipeline programs for safety, efficacy
- Will provide clinical data and leverage for partnering discussions



## **Drug resistant lung cancer: Tribetarna™ Update**



- A single injection of Tribetarna™ effectively silences the βIII tubulin gene
- Tribetarna™ significantly enhances survival in a preclinical model of lung cancer in combination with chemotherapy
- A Phase I/IIa clinical trial of Tribetarna™ in conjunction with cisplatin is being prepared
  - Undertaken prep-preIND meeting with US FDA
  - Manufacture of GLP Product for reg/tox studies underway
  - European CRO appointed CTG CRO

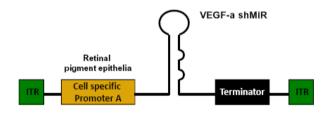


With clinical success in lung cancer, this approach can be developed to target other cancers that express high  $\beta$ III tubulin (breast, ovarian & gastric)

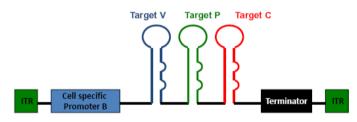


**Age-related macular degeneration** (AMD) – A single injection of a ddRNAi construct to replace current standard of care (monthly injections into the eyeball).

Constructs designed and tested:







- Advanced negotiations for a suitable vector for delivery of ddRNAi therapy
- Research collaborator identified primate model validation



### **Hepatitis B Update**



A replica of TT-034 approach. 350 million people infected worldwide, major unmet medical need – substantial interest from Big Pharma

- Strategy to leverage success of RNAi therapies utilising long term benefit of ddRNAi
- Expanded collaboration with Biomics
  - Sequence validation homology search completed
  - Optimisation of construct in progress
  - Animal model of HBV identified







> Appointed R&D Program Manager to accelerate progress on pre-clinical programs

- > Established laboratory facility in California
  - Recruited 2 scientists ex Tacere supporting Dr Suhy
  - Principle activities
    - Advance pre-clinical testing for AMD, HBV and pain programs
    - Validate alternative DNA manufacturing technology <sup>1</sup>
    - Test and review new delivery options<sup>1</sup>
- ➤ Negotiated enhanced agreement with Professor Yeomans at Stanford University to identify and validate additional targets for Cancer Associated Pain Program
- Identifying and reviewing feasibility of additional ddRNAi disease targets