

silenceworks

SHAREHOLDER UPDATE

Benitec's progress to the clinic with ddRNAi gene-silencing technology

In the past eight months, Benitec Biopharma has made substantial progress towards our ultimate goal - to generate a competitive, appropriate return for stakeholders.

Moving Benitec's programs into the clinic will prove the efficacy and safety of ddRNAi, and will be a significant value inflection point for the company.

Below are the milestones which have moved Benitec steadily towards our goals. At right are two recent major advances which, we believe, justify our confidence in the future.

BREAKING NEWS

June 6, 2013

Benitec secures its 2013 growth plan with A\$7 million capital raise through Private Placement. Further \$3 million to be raised by share purchase plan. [Read more](#) ▶

June 12, 2013

NIH's RAC (Recombinant DNA Advisory Committee) provides favourable early review of Benitec's Hepatitis C therapeutic, TT-034. The next steps expected are formal written recommendations and IND filing with the US FDA. [Read more](#) ▶

Acquiring Tacere Therapeutics and TT-034

October 2012

The acquisition of **Tacere Therapeutics** is a key milestone, providing Benitec with ownership of TT-034, an advanced pre-clinical human therapeutic for Hepatitis C based on ddRNAi technology. TT-034 targets three regions of the Hepatitis C Virus (HCV) genome, thereby greatly reducing the likelihood of viral resistance. As a 'one shot cure' for Hepatitis C, TT-034 is potentially a significant medical breakthrough.

[Read more](#) ▶

Advancing TT-034 to the clinic

December 2012

Benitec's appointment of US-based **Syneract** as its Clinical Research Organisation (CRO) to conduct the TT-034 clinical trial is a major milestone. Syneract will assist in the preparation of regulatory submissions to the US FDA and manage the Phase I/IIa clinical trial of TT-034.

[Read more](#) ▶

Selecting Duke for TT-034 clinical trial

March 2013

Benitec's selection of **Duke University in North Carolina** as a clinical trial site for TT-034 harnesses the expertise of principal investigator, Dr Keyur Patel. Dr Patel is an Australian doctor with extensive experience in Hepatitis C, who won the prestigious American Association for the Study of Liver Diseases (AASLD) Sheila Sherlock Clinical and Translational Research Award.

[Read more](#) ▶

Selecting UCSD for TT-034 clinical trial

April 2013

Selection of the **University of California San Diego** as a clinical trial site for TT-034 brings in the expertise of consultant and sub-principal investigator, Dr Robert Gish. Dr Gish is clinical professor of Medicine and medical director of Hepatology, with extensive experience in using RNAi-based therapeutics for Hepatitis. He is also a fellow of the American College of Physicians and the American Association for the Study of Lung Disease.

[Read more](#) ▶

Submitting TT-034 clinical trial protocol to RAC

April 2013

This document comprises the **full clinical trial protocol for TT-034** and its review by the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH) is standard for clinical trials of any product involving gene therapy vectors.

[Read more](#) ▶

The RAC meeting will be held in Washington, DC, on June 11 with proceedings viewable [here](#) ▶

Advancing the Hepatitis B program

March – May 2013

Progress with the Hepatitis C program has also informed and directed development of another Benitec treatment Hepbarna™ for **Hepatitis B**. Much of the safety and toxicology data from the TT-034 work is expected to be directly relevant and thus should streamline the regulatory path for Hepbarna™.

Progressing with Lung Cancer

March – June 2013

Benitec's collaboration with **CCIA** (Children's Cancer Institute Australia at the UNSW) to reverse chemotherapy resistance in sufferers of **Non Small Cell Lung Carcinoma**, has demonstrated significant silencing and increased survival from one dose of Benitec's ddRNAi-based Tribetarna™.

CCIA's patent on silencing **beta III tubulin** has since been allowed in **China** where lung cancer is the most prevalent cancer type. In addition, Benitec has appointed European-based **Clinical Research Organisation (CRO) Clinical Trials Group** to manage the initial clinical development of Tribetarna™

Adding ex Cephalon CEO to the Board

April 2013

The appointment of former Cephalon CEO **Mr Kevin Buchi** as a Non-Executive Director provides Benitec with significant additional business development strength and networking capacity in the United States and Europe. Mr Buchi led Cephalon through its \$6.8 billion acquisition by Teva Pharmaceutical Industries in 2011. He has an impressive track record in the international biotechnology and pharmaceutical industry covering a 30 year period.

[Read more](#) ▶

Raising awareness of ddRNAi

November 2012-May 2013

Benitec is active in promoting awareness of **ddRNAi technology**, its uses, its importance and the promise it holds. Progress in Benitec's programs has been presented at the **Ausbiotech Investor Showcase** (Melbourne, November 2012), **JP Morgan – Cowen Biotech Showcase** (San Francisco, January 2013), **Cappello Australia – US Investment Conference** (Los Angeles, January 2013), **Ausbiotech US Investor Showcase** (New York, April 2013) and at the **International Association for the Study of Pain summit** (London, May 2013).

Raising Benitec's profile

April-May 2013

The company is also actively **raising its profile as an innovator and leader in gene-silencing**, with **ABC TV's The Business** (interview with Dr Peter French and Dr Michael Graham), **Radio 2GB's Steve Price** (interview with Dr Peter French), a Benitec Biopharma **Wikipedia page**, a **Lodge Partners Research** report (noting 'very exciting time' for Benitec and maintaining 'buy' recommendation), a **Bioshares Report** (reporting on the Buchi appointment and recommending Speculative Buy Class A) and a **ddRNAi animated video** (explaining how the technology works, highlighting treatment of Hepatitis B and C).

Setting new targets

Rest of 2013

Benitec is working actively to achieve these goals in 2013: **Hepatitis C** first-in-man phase I/IIa trial in Hepatitis C, **HIV/AIDS** first dosing in humans of licensee Calimmune's treatment, **Lung Cancer** (NSCLC) preliminary FDA meeting for therapeutic program, **animal model Proof of Concept** data for other pipeline therapeutics, and **building data** to support ongoing discussions with potential partners.