

# **ASX/NASDAQ ANNOUNCEMENT**

# Interim Report for the Nine Months Ended March 31, 2016

**Sydney, Australia - May 24, 2016 -** Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) today lodged its Interim Report for the nine months ended March 31, 2016. The report includes the financial results and a review of operations for the period.

### Summary of the key points from the Interim Report:

- The net loss for the nine months was \$A18.5 million and included research and development spending of AU\$11.1 million. Benitec's current assets at March 31, 2016 were A\$26.5 million.
- In March 2016 Benitec announced encouraging results of its recent *in vivo* efficacy study of BB-HB-331. Key findings indicate that a single BB-HB-331 treatment in the PhoenixBio mouse model can result in suppression of hepatitis B (HBV). These results demonstrate the potential utility of an approach that combines RNAi with gene therapy to treat HBV, and the Company intends to advance the HBV program towards the clinic.
- On February 26, 2016 Benitec announced that it would wind-down its hepatitis C program and terminate the program upon completion of patients in Cohort 4 in its Phase I/IIa clinical trial for TT-034.
- In December 2015, Benitec announced positive *in vitro* data demonstrating the efficacy of BB-HB-331 and supporting the progression of BB-HB-331 into *in vivo* preclinical testing. The data was presented at the HEPDART 2015 conference in the US in December 2015.
- In August 2015, Benitec completed a NASDAQ listing raising A\$18.8 million (US\$13.8 million) before costs.
- In July 2015, Benitec announced it acquired full rights to its preclinical DNA-directed RNA interference based hepatitis B therapeutic program for \$2.5 million. The program was previously a joint development collaboration between Benitec and Biomics.
- Benitec anticipates completing in vivo preclinical proof of concept studies for age-related macular degeneration ('AMD') and oculopharyngeal muscular dystrophy ('OPMD') by the end of calendar year 2016

#### **Webcast Information and Conference Call:**

The Company will host a live audio webcast and conference call on Wednesday, March 25 at 8:00am AEST (Australian Eastern) and simultaneously on Tuesday, March 24 at 6.00pm EDT (US Eastern Daylight Savings Time), to provide an operational and financial update.

To access the live webcast please enter <a href="http://services.choruscall.com/links/bntc160523">http://services.choruscall.com/links/bntc160523</a> into your internet browser. Investors will be able to submit questions in writing via the webcast, to be addressed by Benitec's management during the call.

To access the conference call, please use the dial in details below.

Conference ID: 902026

US dial in: +1 855-624-0077



Australia dial in: 1800 908 299 or 1800 455 963

All other locations dial: +61 2 9007 8048

Shareholders are encouraged to use the webcast link, as conference call lines are limited. An archive of the webcast will remain available on Benitec's website for 90 days beginning at approximately 9:30am AEST on 25 May 2016.

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**

MarketEye Orla Keegan Director

Tel: +61 (2) 8097 1201

Email: orla.keegan@marketeye.com.au

#### **United States Investor Relations**

PCG Advisory Group Adam Holdsworth Managing Director of Investor Relations Tel: +1 646-862-4607

Email: adamh@pcgadvisory.com

Sean Leous Managing Director of Public Relations Tel: +1 646-863-8998

Email: sleous@pcgadvisory.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 labs in Hayward, CA (USA) and collaborators and licensees around the world, the company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including hepatitis B, wet age-related macular degeneration and OPMD. Benitec has also licensed ddRNAi to other biopharmaceutical companies for applications including HIV/AIDS, Huntington's Disease, chronic neuropathic pain 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 commercialize 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.



ABN 64 068 943 662

# **Interim Report**

for the nine months ended March 31, 2016

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The information in this report should be read in conjunction with the most recent annual financial report and any public announcements made by Benitec Biopharma Limited.

# **Results for Announcement to the Market**

# for the nine months ended March 31, 2016

#### 1. Reporting period

The financial information contained in this report is for the nine months ended March 31, 2016. Comparative amounts for the Consolidated Statement of Profit or Loss and Other Comprehensive Income are the nine months ended March 31, 2015. Financial Position comparatives are at June 30, 2015.

#### 2. Results for Announcement to the Market

		Change	% Change	\$A'000
2.1	Revenue from ordinary activities	down	(41%)	385
2.2	(Loss) from ordinary activities after tax attributable to members	up	195%	(18,528)
2.3	Net (loss) for the period attributable to members	up	195%	(18,528)
2.4	The amount per security and franked amount per security of final and interim dividends	No dividends w period	ere declared	or paid during the
2.5	A brief explanation of any of the figures in 2.1 to 2.3 necessary to enable the figures to be understood	from the Benited	Biopharma Lin	which was extracted mited interim report ch 31, 2016 which nt

### 3. Commentary on results for the period

Benitec's comprehensive loss for the nine months to March 31, 2016 was A\$18.5 million compared to a comprehensive loss of A\$6.3 million for the previous corresponding period.

Operating revenue was A\$0.21 million compared to A\$0.20 million in the previous corresponding period. Operating expenses were A\$22.5 million compared with operating expenses in the previous period of A\$9.8 million.

The nine month loss includes research and development spending of A\$11.1 million compared to A\$4.2 million in the previous corresponding period. Benitec acquired full rights to its preclinical hepatitis B program from its collaborator, Biomics Biotechnologies, for A\$2.5 million with plans to independently progress the product candidate in this therapeutic field.

Benitec's current assets at March 31, 2016 were A\$26.5 million (June 30, 2015: A\$25.1 million), with current liabilities of A\$2.2 million (June 30, 2015: A\$1.6 million).

# 4. Net tangible asset backing per share

	March 2016	June 2015
Net tangible asset backing per ordinary share	17.0 cents	20.6 cents

# **Company History**

Benitec Biopharma Limited was incorporated under the laws of Australia in 1995 and has been listed on the Australian Securities Exchange, or ASX, since 1997. Since then, we have devoted the majority of our resources to development of therapeutic agents related to DNA-directed RNA interference (ddRNAi). While we have established some licensing arrangements, we do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily from private placements of ordinary shares, including A\$31.5 million of gross proceeds raised in February 2014, and our U.S. initial public offering in August 2015, the gross proceeds from which equalled A\$18.8 million (U.S.\$13.8 million). We have also received research and development grants from the Australian federal government, totalling A\$2.3 million in fiscal year 2015 and have earned licensing revenue from licensing our ddRNAi technology to five biopharmaceutical companies, totalling A\$0.3 million in the same period.

In October 2012, we acquired Tacere Therapeutics, Inc., an RNA interference therapeutics company based in California with a development program focused on hepatitis C and age related macular degeneration (AMD). As consideration for the acquisition, we issued a total of 4,092,854 ordinary shares (taking into account a 25:1 share consolidation that became effective in July 2013), representing 9.8% of our issued capital immediately after the transaction, having an aggregate value of A\$1.5 million.

In August 2015, we completed our US initial public offering in which we issued 30,000,000 ordinary shares (represented by 1,500,000 ADSs) and 575,000 Warrants, and we listed the ADSs and Warrants on The NASDAQ Capital Market.

Our headquarters are located at F6/1-15 Barr St, Balmain, New South Wales, 2041, Australia. Our telephone number is +61 2 9555 6986. Our website address is www.benitec.com.

#### **General information**

The financial statements cover Benitec Biopharma Limited as a Group consisting of Benitec Biopharma Limited and the entities it controlled at the end of, or during, the nine month period ended March 31, 2016. The financial statements are presented in Australian dollars, which is Benitec Biopharma Limited's functional and presentation currency.

Benitec Biopharma Limited is a listed public company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is F6/1-15 Barr Street, Balmain, New South Wales, 2041, Australia.

A description of the nature of the Group's operations and its principal activities are included in the Directors' report, which is not part of the financial statements.

The financial statements were authorised for issue, in accordance with a resolution of directors, on May 24, 2016. The directors have the power to amend and reissue the financial statements.

The Company's directors and management are committed to conducting the Group's business in an ethical manner and in accordance with the highest standards of corporate governance. The Company has adopted and substantially complies with the ASX Corporate Governance Principles and Recommendations (3rd Edition) ('Recommendations') to the extent appropriate to the size and nature of the Group's operations.

The Company has prepared a Corporate Governance Statement which sets out the corporate governance practices that were in operation throughout the financial reporting period for the Company, identifies any Recommendations that have not been followed, and provides reasons for not following such Recommendations.

The Company's Corporate Governance Statement and policies, which were approved by the Board of directors on August 31, 2015 can be found on its website: <a href="http://www.benitec.com/investor-centre/governance">http://www.benitec.com/investor-centre/governance</a>.

# **Explanatory Notes**

Unless otherwise indicated or the context implies otherwise:

- "we", "us," "our" or "Benitec" refers to Benitec Biopharma Limited, an Australian corporation, and its subsidiaries;
- "shares" or "ordinary shares" refers to our ordinary shares;
- "ADSs" refers to American Depositary Shares, each of which represents 20 ordinary shares;
- "ADRs" refers to American Depositary Receipts, which evidence the ADSs; and
- "Warrant" refers to a warrant to purchase one ADS at an exercise price of U.S.\$5.50 per ADS, exercisable from the date of issuance until five years thereafter.

Our reporting and functional currency is the Australian dollar. Solely for the convenience of the reader, this document contains translations of some Australian dollar amounts into US dollars at specified rates. Except as otherwise stated in this document, all translations from Australian dollars to US dollars are based on the rate published by the Reserve Bank of Australia on the date indicated. No representation is made that the Australian dollar amounts referred to in this document could have been or could be converted into US dollars at such rate.

Unless otherwise noted, all other financial and other data related to Benitec Biopharma Limited in this document are presented in Australian dollars. All references to "\$" in this document refer to Australian dollars or US dollars, as the context requires based on the foregoing. All references to "A\$" in this document mean Australian dollars. All references to "U.S.\$" in this document mean US dollars. Our fiscal year end is June 30. References to a particular "fiscal year" are to our fiscal year ended June 30 of that calendar year.

Unless otherwise indicated, the consolidated financial statements and related notes included in this document have been prepared in accordance with AASB 134 Interim Financial Reporting and also comply with International Financial Reporting Standards, or IFRS, and interpretations issued by the International Accounting Standards Board, or IASB, which differ in certain significant respects from Generally Accepted Accounting Principles in the United States, or GAAP.

# **Forward-Looking Statements**

This document contains "forward-looking statements" within the meaning of section 27A of the US Securities Act of 1933 and section 21E of the U.S. Securities Exchange Act of 1934. The Company has tried to identify such forwardlooking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to, any statements relating to Benitec's pipeline of ddRNAi-based therapeutics, including the initiation, progress and outcomes of clinical trials and any other statements that are not historical facts. Such forward-looking statements involve risks and uncertainties, including, but not limited to, risks and uncertainties relating to the difficulties or delays in our plans to develop and potentially commercialise our 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 our product candidates, potential future outlicenses and collaborations, our intellectual property position and duration of our patent portfolio, the ability to procure additional sources of financing and other risks detailed from time to time in filings that the Company makes with the ASX and US Securities and Exchange Commission, including our most recent annual report on Form 20-F and our reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this report. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.

The forward-looking statements made in this document relate only to events or information as of the date on which the statements are made in this document. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events.

# **Directors' Report**

# for the nine months ended March 31, 2016

The Company's Directors present their report on the consolidated entity consisting of Benitec Biopharma Limited ('Company') and the entities it controlled ('Group') at the nine months ended March 31, 2016.

#### **Directors**

The following persons were directors of Benitec Biopharma Limited (the 'Company' or 'Benitec') during the whole of the period and up to the date of this report, unless otherwise noted:

Mr. Peter Francis (Chairman)

Mr. Kevin Buchi

Dr John Chiplin

Mr. Iain Ross

Dr Peter French (retired December 9, 2015)

#### **Financial Update**

Benitec's comprehensive loss for the nine months to March 31, 2016 was A\$18.5 million compared to a comprehensive loss of A\$6.3 million for the previous corresponding period.

Operating revenue was A\$0.21 million compared to A\$0.20 million in the previous corresponding period. Operating expenses were A\$22.5 million compared with operating expenses in the previous period of A\$9.8 million.

The nine month loss includes research and development spending of A\$11.1 million compared to A\$4.2 million in the previous corresponding period. Benitec acquired full rights to its preclinical hepatitis B program from its collaborator, Biomics Biotechnologies, for A\$2.5 million with plans to independently progress the product candidate in this therapeutic field.

Benitec's current assets at March 31, 2016 were A\$26.5 million (June 30, 2015: A\$25.1 million), with current liabilities of A\$2.2 million (June 30, 2015: A\$1.6 million).

### **REVIEW OF OPERATIONS**

Benitec's novel, proprietary therapeutic technology combines gene silencing and gene therapy with a goal of providing sustained, long-lasting silencing of disease-causing genes from a single administration. DNA-directed RNA interference ('ddRNAi') is being used to develop a pipeline of product candidates for the treatment of numerous chronic and life-threatening human diseases, such as hepatitis B ('HBV'), age-related macular degeneration ('AMD'), and oculopharyngeal muscular dystrophy ('OPMD').

By combining the specificity and gene silencing effect of RNA interference with gene therapy, ddRNAi has the potential to produce long-lasting silencing of disease-causing genes from a single administration, which could eliminate the requirement for patient compliance to take regular doses of medicine for long-term management of their disease.

The Company has set the following priorities:

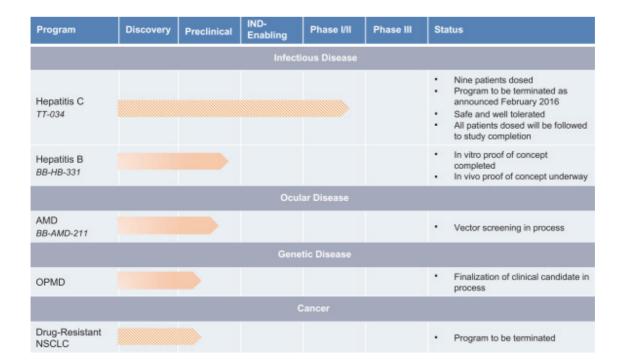
- Progress its pipeline of proprietary ddRNAi-based therapeutics
  - On February 26, 2016 the Company announced that it would wind-down its hepatitis C program and terminate the program upon completion of patients in Cohort 4 in its Phase I/IIa clinical trial for TT-034. Further detail on the termination of the program is included in 'in house Programs' later in this report.

Benitec is committed to completing the collection of trial data and monitoring patients through the required four and a half year long-term safety follow-up period. Final data supporting the primary and secondary endpoints of the study will be reported in Q4 2016 when the study is completed. Although the hepatitis C program is being discontinued, it is important to note that early stage TT-034 clinical trial results indicated TT-034 was safe and well tolerated, meeting the primary endpoint of the study and, as such, will assist in other programs.

- The other three therapeutic indications (HBV, AMD and OPMD) are being progressed through their respective stages in the development pathway. The Company anticipates having completed in vivo preclinical proof of concept studies for all three indications by the end of calendar year 2016. The Company will require additional financing to conduct clinical trials with these product candidates. Further detail of individual programs is provided in subsequent sections of this Review and Results of Operations.
- Continue the Company's leadership position in ddRNAi-based therapeutics
  - Benitec remains the only company to date to advance an RNAi therapeutic via systemic administration by gene therapy vectors.
- Further develop and improve the ddRNAi platform technology and its associated intellectual property position
  - Develop in-house, ddRNAi platform technology and program related intellectual property, and inlicense complementary technologies, as appropriate, to support the product pipeline. One such example is the Company's relationship with 4D Molecular Therapeutics LLC (4DMT) to develop a suitable vector to deliver the Company's ddRNAi constructs to a large majority of the retinal cells of the eye from a single intravitreal injection to treat human ocular diseases.
- Develop drug candidates in Benitec's core disease areas and partner selectively to commercialise and expand the Company's pipeline
  - Selectively form collaborations to expand the Company's capabilities and product offerings into a range of diseases and potentially to accelerate the development and commercialisation of ddRNAi therapeutics more broadly.
  - Advance programs in core disease areas to appropriate stage of proof of concept to commercialise
    with pharmaceutical companies. As an example, Benitec acquired full rights to its preclinical hepatitis B
    program from its collaborator, Biomics Biotechnologies, to enable the independent progression of the
    product candidate and simplify partnering negotiations.
  - Where appropriate we seek to progress one or more programs through to commercialisation. For example, Benitec's pipeline program to treat an orphan indication, OPMD, is seen as a candidate for this approach.
  - Out-license use of ddRNAi for applications and therapeutics outside of the Company's immediate focus to expand Benitec's franchise of ddRNAi-based therapeutics. As an example, Benitec licensed ddRNAi to Circuit Therapeutics to develop the technology in the area of intractable pain.
- Pursue indications with high unmet medical need or large patient populations
  - Programs currently being pursued at Benitec are severe diseases with high unmet medical need or large patient populations that have well characterised gene targets that can be silenced, thus preventing the disease-causing gene from being expressed.
  - o The Company also intends to develop ddRNAi applications in novel technologies, such as chimeric antigen receptor T cells, or CAR -T, for a range of additional disease areas.

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#### **In-house Programs**



As of March 31, 2016, Benitec has three pipeline programs in development. Using the capital raised from the successful NASDAQ listing in August 2015 and the capital raised in April 2014, the Company continues to progress these development programs. Highlights of progress over the previous 9 months include:

- (1) **Hepatitis B BB-HB-331:** The Company is developing BB-HB-331 for the treatment of HBV, which infects up to 240 million people worldwide, resulting in up to 780,000 deaths per year. The key features and milestones of the HBV program are as follows:
  - BB-HB-331 is designed to be a single administration ddRNAi-based monotherapy or to be used in combination therapy with other anti-viral medications. BB-HB-331 is delivered using a gene therapy vector that targets the liver and inhibits viral replication as well as restricts viral RNA levels and subsequent HBV protein production on a long-term basis. As both HBV and HCV replicate in the liver, Benitec has designed BB-HB-331 to mimic the design elements of TT-034, which might expedite the regulatory pathway of this drug;
  - In July 2015 the Company acquired full rights to BB-HB-331 from China-based Biomics Biotechnologies.
     To facilitate independent development and simplify partnering opportunities, Benitec made the decision to develop BB-HB-331 as a solely-owned program;
  - In October 2015 the Company entered into a Manufacturing Services Agreement with Lonza, Inc. to develop a scalable manufacturing process for Benitec's ddRNAi products delivered by Adeno-Associated Virus (AAV) capsids;
  - o In December 2015 the Company announced positive *in vitro* data demonstrating the efficacy of BB-HB-331 and supporting the progression of BB-HB-331 into *in vivo* preclinical testing. The data was presented at the HEPDART 2015 conference in the US in December 2015;

- o In March 2016 the Company announced results of its recent *in vivo* efficacy study of BB-HB-331. Key findings of the *in vivo* study indicate that a single BB-HB-331 treatment in the PhoenixBio (PXB) mouse model can result in suppression of HBV. These results demonstrate the potential utility of an approach that combines RNAi with gene therapy to treat HBV, and the Company intends to advance the HBV program towards the clinic. The hepatitis B program continues to attract considerable interest from pharmaceutical companies; and
- O Subject to additional financing, the Company plans to file an investigational new drug ('IND') application in the third calendar quarter of 2017.
- (2) Age-related macular degeneration ('AMD'): AMD is the leading cause of irreversible vision loss in the United States, affecting an estimated 1.75 million people and it is estimated that 196 million people will be affected by AMD worldwide by 2020. The aim of this program is to develop a therapeutic that provides long-term treatment of AMD from a single intravitreal injection. The Company believes this could replace the need for regular injections of therapeutics into the eye, which is the current standard of care. The key milestones achieved over the last 12 months and next steps include:
  - Three ddRNAi-based therapies are in development BB-AMD-211 and BB-AMD-233 for the treatment
    of wet AMD and BB-AMD-231 for the treatment of both wet and dry AMD;
  - The Company has entered into collaboration with 4D Molecular Therapeutics (4DMT) for the development of the delivery vector for ocular-based ddRNAi products. Due to the need for an extra round of screening, vector development is now expected to be completed in the second quarter of 2016 but continues to show excellent progress towards identifying novel capsids;
  - o In vivo proof of concept studies are expected to be completed by the end of calendar year 2016; and
  - Subject to additional financing, the Company plans to file an IND application by the end of calendar year 2017.
- Oculopharyngeal Muscular Dystrophy (OPMD): Benitec is developing a ddRNAi treatment for the treatment of OPMD. In this novel treatment the Company is developing a "knock down & replace" approach, silencing a mutant gene in conjunction with its replacement with healthy wild type gene. OPMD is an autosomal-dominant inherited, slow-progressing, late-onset degenerative muscle disorder that usually starts in patients during their 40s or 50s. The disease is manifested by progressive swallowing difficulties (dysphagia) and eyelid drooping (ptosis). OPMD is caused by a specific mutation in the poly(A)-binding protein nuclear 1, or PABPN1, gene. OPMD is a rare disease and has been reported in at least 33 countries. Patients suffering with OPMD are well identified and are aggregated in particular regions, which we believe should simplify clinical development and in house commercialisation. Key milestones achieved over the last 12 months and next steps include:
  - Preliminary *in vivo* studies in an animal model of OPMD have been completed and the results support
    the proof of concept of this approach with individual components. This data was presented at the
    13th Annual Meeting of the British Society for Gene and Cell Therapy that was held in London, U.K. on
    April 15, 2016;
  - In August 2015 the Company signed an extension to the Collaboration Agreement with Royal Holloway University of London. Work is ongoing to finalise the proposed clinical candidate and to optimise the *in vivo* delivery; and
  - The Company plans to progress the program through *in vivo* proof of concept with the proposed clinical candidate by the end of calendar year 2016.

**Hepatitis C – 'TT-034':** On February 26, 2016 the Company announced that, due to a lack of a sustainable commercial path, it would wind-down a partially completed Phase I/IIa clinical trial for its now discontinued product candidate, TT-034.

Early data from the clinical trial of TT-034 indicated that TT-034 was safe and well-tolerated, meeting the primary endpoint of the study. However, as a result of the increasingly competitive landscape among available HCV therapies, in February 2016 the Company concluded that the TT-034 program no longer offered the commercial value necessary to attract a worthwhile commercial partnership deal and, as a result, did not warrant additional expenditure or focus of its resources beyond completion of the existing patients. The Company believes the early stage TT-034 clinical trial results provide valuable data that supports and validates the company's ddRNAi technology platform and other pipeline programs, particularly liver-based indications. Benitec is committed to completing the collection of trial data and monitoring patients through the required long-term safety follow-up period.

#### The key achievements over the reporting period for the HCV program are as follows:

- The four clinical sites participating in the study include the Duke Clinical Research Unit, University of California San Diego, the Texas Liver Institute and Methodist Health System Clinical Research Institute in Dallas;
- Nine patients have been dosed to date; and
- Data from patients in the early cohorts were presented at the American Association for the Study of Liver Diseases (AASLD) conference in San Francisco in December 2015. This data indicates that a single infusion of TT-034 is reaching the liver and has a favourable safety profile. These interim results on safety and clinical activity are in line with expectations.

Benitec remains focused on advancing its other pipeline programs, including hepatitis B, age-related macular degeneration (AMD) and oculopharyngeal muscular dystrophy (OPMD). The Company believes that each of these programs presents attractive commercial opportunities. In particular, the hepatitis B program is attracting considerable interest from pharmaceutical companies. Based on this interest, the promising *in vivo* data announced in March, and the significant potential market opportunity, Benitec will now prioritise the hepatitis B program as its next candidate for clinical development.

Benitec is committed to completing the collection of all trial data and monitoring patients through the required long-term safety follow-up period for the HCV trial. In addition, final data supporting the primary and secondary endpoints of the study will be reported in the last quarter of 2016 calendar year once the study is completed.

#### **Licensed programs**

In addition to the Company's in-house development programs, Benitec has licensed its ddRNAi technology to companies who are developing therapeutic programs in five disease areas. Each of them provides a potential opportunity for further clinical validation of the technology and potential revenue opportunity. These licenses have been granted to small early-stage biotechnology companies with modest upfront and early development milestone payments and greater milestone payments due upon later-stage program success.

The following table sets forth our out-licensed product candidates and their development status.

Focus	Indication	Product Candidate	Company	Discovery	Preclinical	Phase VIIa
Infectious Disease	HIV/AIDs	Cal-1	Calimmune			
Cancer	Cancer Immunotherapy	dCellVax	Regen Biopharma			
Ocular Disease	Retinitis Pigmentosa	RhoNova	Genable			
Genetic Disease	Huntington's Disease		uniQure			
Central Nervous System	Intractable Neuropathic Pain		Circuit Therapeutics			

- HIV/AIDS: In March 2012, Benitec granted a non-exclusive, royalty-bearing, worldwide license to a U.S.-based biotechnology company, Calimmune, Inc., (Calimmune). Under the agreement, Calimmune can develop, use and commercialize ddRNAi to silence up to three targets for the treatment or prevention of HIV/AIDS. Calimmune's approach was developed with core technology from the laboratory of Dr. David Baltimore, a Nobel Laureate in the area of HIV/AIDS, and involves silencing the gene that codes for a receptor protein known as CCR5. Calimmune's HIV/AIDS treatment is known as Cal-1.
  - In 2014, Calimmune commenced a Phase I/IIa clinical trial of Cal-1. The goal of the trial is to assess the safety of the therapy, to determine the ease of use and feasibility of the approach for HIV/AIDS patients and to evaluate what, if any, side effects there may be. As of early 2016 Calimmune reported that, following review by the DSMB of the first cohort of patients for the trial, a second patient cohort was dosed, consisting of four patients, who received a preconditioning regimen designed to make the treatment more effective.
- Cancer Immunotherapy: In August 2013, Benitec granted an exclusive, royalty-bearing, worldwide license to a U.S.-based biotechnology company, Regen Biopharma Inc., (Regen), to use ddRNAi for silencing expression of indoleamine 2,3—dioxygenase, or IDO, in dendritic cells. Regen is developing a cancer immunotherapy using the licensed technology. IDO is associated with immune-suppression and is overexpressed in some cancers. Regen has reported preclinical evidence that modification of these cells using RNAi targeting the silencing of IDO may significantly enhance their efficacy in cancer immunotherapy. Regen's first treatment, which is for breast cancer, is called dCellVax.

- In November 2014, Regen announced the FDA had issued an IND number for a proposed Phase I/II clinical trial assessing safety with signals of efficacy for dCellVax.
- Retinitis Pigmentosa: In July 2012, Benitec granted an exclusive, royalty-bearing, worldwide license to an Ireland-based biotechnology company, Genable Technologies Limited (Genable), to use, develop or commercialise RNAi for treatment or prevention of retinitis pigmentosa. Genable's treatment involves suppression of the mutant and normal genes, and replacement with a normal RHO gene that has been modified to be resistant to ddRNAi gene silencing. Genable has reported that it established proof of concept in an in vivo model of the disease. Genable's treatment for retinitis pigmentosa, GT308, is named RhoNova.
  - In October 2014, the European Medicines Agency, (EMA), granted RhoNova Advanced Therapy Medicinal Product classification. The classification enables Genable to procure centralized scientific advice and guidance from EMA regulators on RhoNova's ongoing development. In 2013, the FDA granted Genable orphan drug designation for RhoNova. In March 2016, Genable announced that Spark Therapeutics had acquired the company for a combination of cash and common stock. Spark Therapeutics has indicated support for continuing the development of RhoNova.
- Huntington's disease: In December 2012, Benitec granted a non-exclusive, royalty-bearing, worldwide license to a Netherlands-based biotechnology company, uniQure biopharma B.V. (uniQure), to use, develop or commercialize RNAi for treatment of Huntington's disease. Our license grants to uniQure rights to develop, use and commercialize an AAV vector with a ddRNAi cassette targeting the gene associated with Huntington's disease, or the Htt gene, or an AAV-RNAi-based product for Huntington's disease directed to up to three gene targets specific to Huntington's disease.
  - In May 2013, uniQure announced that it, along with its partners in a pan-European consortium devoted to finding a gene therapy cure for Huntington's disease, were awarded a 2.5 million Euros grant for use in the development of a RNAi-based approach. uniQure has reported that it is using RNAi to non-specifically knock down all expression of the HTT gene and to specifically inhibit the mutant allele of the HTT gene. Evaluation of these two approaches is in progress.
- Intractable Neuropathic Pain: U.S.-based biotechnology company, Circuit Therapeutics, is using ddRNAi to develop treatments for the prevention of pain. Under the licensing agreement, the company has the rights to develop and commercialise treatments that use ddRNAi to silence Nav1.7, a sodium ion channel that is exclusively expressed in certain sensory nerves and is critical for generation of pain. In November 2014, we granted an exclusive, royalty-bearing, worldwide license to a US-based biotechnology company, Circuit Therapeutics, Inc. (Circuit Therapeutics), to use ddRNAi for the development of treatments for and the prevention of pain. Under the licensing agreement, Circuit Therapeutics has rights to develop, use and commercialize treatments that use ddRNAi to silence Nav1.7.

#### Intellectual property

Benitec's objective is to protect the intellectual property and proprietary technology that is important to the Company's business, which includes seeking and maintaining patents for the ddRNAi platform technology that is licensed from CSIRO, and other inventions relating to products in development, or otherwise commercially and/or strategically important to the development of the Company's business. The patent estate of technology and program-specific patents continues to progress with patents being granted in existing patent families, and with new patent filings to capture inventions as programs develop.

#### Key developments:

• International patent filing for AMD program entered National Phase in multiple jurisdictions that were identified as key markets for age-related macular degeneration, including Australia, Canada, China, Europe, Israel, Japan, Korea, Mexico, Russia, Singapore, South Africa, and the U.S.;

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- The decision of the European patent office to revoke Graham patent EP1555317 was jointly appealed by Benitec and CSIRO. An appeal was heard by the European patent office on May 13, 2016 and a decision is pending. Once issued, the decision will be communicated by the Company;
- Patents have been granted in the US, Canada, and Europe (validated in Denmark, France, Germany, Sweden, Switzerland, the Netherlands, and the U.K.) in the patent family entitled "RNAi expression constructs"; the invention in this family is directed to the triple short hairpin RNAs (shRNAs) of TT-034 expressed by a single promoter;
- Patent has been granted in the US, with allowances also published in the U.S. and Europe in the patent family entitled "HBV treatment"; the invention in this family is directed to HBV sequences that were jointly developed with Biomics Biotechnologies; the patent family is now assigned to Benitec;
- Provisional patent application was filed in the US for new sequences developed at Benitec in the HBV program, capturing *in vitro* and *in vivo* data generated using Benitec's constructs; and
- New patent filings are in preparation for the HBV and OPMD programs.

#### Commercialisation

Business development remains a major focus for Benitec, consistent with the Company's strategy to:

- Partner pipeline programs with other biotechnology and pharmaceutical companies at major value inflection points,
- Establish co-development and collaboration arrangements for non-pipeline projects with pharmaceutical companies using the ddRNAi platform, and
- Out-license ddRNAi to companies who are developing therapeutics independently.

During the last nine months there has been a significant increase in engagement with 'Big Pharma'. The Company continues to generate strong interest from a number of potential partners with a particular focus on hepatitis B, AMD and the ddRNAi platform.

### Shareholdings by each director and other members of key management

The number of shares in the Company held during the period by each director and other members of key management personnel (KMP) of the Group, including their personally related parties, is set out below:

		Received as			
	Balance at 1 July 2015	part of remuneration	Exercise of options	Disposals /other	Balance at 31 March 2016
Ordinary shares					
Peter Francis	424,174	-	-	-	424,174
Kevin Buchi	861,539	-	-	-	861,539
John Chiplin	200,000	-	-	-	200,000
lain Ross	66,364	-	-	-	66,364
Peter French	591,785	-	-	-	591,785
Carl Stubbings	136,787				136,787
	2,280,649				2,280,649

None of the shares are held nominally by the key management personnel.

# Option holdings by each director and other members of key management

The number of options over ordinary shares in the Company held during the financial period by each director and other members of key management personnel of the Group, including their personally related parties, is set out below:

	Balance at 1 July 2015	Granted*	Exercised	Expired /forfeited other	Balance at 31 March 2016	Vested and exercisable	Vested and un- exercisable
Options over ordinary shares	July 2013	Granted	Lxercised	otnei	2010	exercisable	exercisable
Peter Francis	1,600,000	1,400,000	-	-	3,000,000	2,066,666	-
Peter French	2,600,000	2,800,000	-	(5,400,000)	-	-	-
Kevin Buchi	400,000	840,000	-	-	1,240,000	680,000	-
John Chiplin	400,000	840,000	-	-	1,240,000	680,000	-
lain Ross	400,000	840,000	-	-	1,240,000	680,000	-
Carl Stubbings	1,000,000	-	-	-	1,000,000	800,000	-
David Suhy	1,200,000	-	-	-	1,200,000	933,334	-
Greg West	1,000,000	-	-	-	1,000,000	706,666	-
Georgina Kilfoil	600,000				600,000	400,000	-
	9,200,000	6,720,000		(5,400,000)	10,520,000	6,946,666	<u>-</u>

<sup>\*</sup>Options were granted at the Annual General Meeting held on November 12, 2015

#### Other transactions with key management personnel and their related parties

Payments totalling \$67,906 were made to Francis Abourizk Lightowlers (a law firm in which Peter Francis is a partner and has a beneficial interest) for legal services at normal commercial rates in the nine months ended to March 31, 2016 (nine months ended March 31, 2015: \$80,672).

Consultancy fees totalling \$113,559 were paid for executive duties in the nine months to March 31, 2016 (nine months ended March 31, 2015: \$42,000) to Newstar Ventures Ltd, a corporation in which John Chiplin is a director and has a beneficial interest.

Signed in accordance with a resolution of the directors.

**Peter Francis** 

Director

Melbourne, May 24, 2016



Level 17, 383 Kent Street Sydney NSW 2000

Correspondence to: Locked Bag Q800 QVB Post Office Sydney NSW 1230

T +61 2 8297 2400 F +61 2 9299 4445 E info.nsw@au.gt.com W www.grantthornton.com.au

# Auditor's Independence Declaration To The Directors of Benitec Biopharma Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the review of Benitec Biopharma Limited for the nine months ended 31 March 2016, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b no contraventions of any applicable code of professional conduct in relation to the review.

GRANT THORNTON AUDIT PTY LTD

Chartered Accountants

N/J Bradley

Partner - Audit & Assurance

Sydney, 24 May 2016

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# **Consolidated Statement of Profit or Loss and Other Comprehensive Income**

FOR THE NINE MONTHS ENDED MARCH 31, 2016

		Nine Months ended		
	Notes March		March	
		2016	2015	
		\$'000	\$'000	
Revenue	2	385	649	
Other Income	2	3,600	2,876	
Expenses				
Royalties and licence fees		(79)	(40)	
Research and development		(11,098)	(4,176)	
Employee benefits expense		(4,940)	(2,331)	
Share-based expense		(1,530)	(1,035)	
Travel related costs		(893)	(778)	
Consultants costs		(920)	(637)	
Occupancy costs		(391)	(238)	
Corporate expenses		(923)	(571)	
Foreign exchange translation		(762)	-	
IPO costs		(977)	-	
Loss before income tax	_	(18,528)	(6,281)	
Income tax		-	(1)	
Loss after income tax for the period attributable to the	_	(10.500)	(5,000)	
owners of Benitec Biopharma Limited		(18,528)	(6,282)	
Other comprehensive income	_	-		
Other comprehensive income for the period, net of tax		(53)	43	
Total comprehensive loss for the period attributable to the	-	(18,581)	(6,239)	
owners of Benitec Biopharma Limited	-	(18,581)	(6,239)	
Basic earnings (loss) for the nine month period, cents per		(13.2)	(5.4)	
share  Diluted earnings (loss) for the nine month period, cents per		, ,	, ,	
Diluted earnings (loss) for the nine month period, cents per share		(13.2)	(5.4)	

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

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# **Consolidated Statement of Financial Position**

FOR THE NINE MONTHS ENDED MARCH 31, 2016

	Notes	March 2016 \$'000	June 2015 \$'000
ASSETS			
Current Assets			
Cash and cash equivalents		19,878	21,787
Trade and other receivables		32	123
Other	5	6,558	3,154
Total Current Assets	_	26,468	25,064
Non-current Assets			
Plant and equipment		597	456
Total Non-current Assets		597	456
TOTAL ASSETS	_	27,065	25,520
LIABILITIES			
Current Liabilities			
Trade and other payables	6	2,084	1,449
Provisions		127	193
Total Current Liabilities	_	2,211	1,642
Non-Current Liabilities			
Provisions		17	
Total Non-Current Liabilities		17	
TOTAL LIABILITIES	_	2,228	1,642
NET ASSETS	<u>-</u>	24,837	23,878
EQUITY			
Issued capital	7	147,641	129,631
Reserves		2,314	2,038
Accumulated losses		(125,118)	(107,791)
TOTAL EQUITY	_	24,837	23,878

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

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# **Consolidated Statement of Changes in Equity**

FOR THE NINE MONTHS ENDED MARCH 31, 2016

	Issued capital \$'000	Reserves \$'000	Accumulated Losses \$'000	Total equity \$'000
Consolidated				
Balance at June 30,2014	129,186	641	(96,286)	33,541
Loss for the nine month period	-	-	(6,282)	(6,282)
Other comprehensive income	-	43	-	43
Total comprehensive income Contributions of equity, net of transaction	-	43	(6,282)	(6,239)
costs	310	-	-	310
Share based payments	-	1,035	-	1,035
At March 31, 2015	129,496	1,719	(102,568)	28,647
Balance at June 30, 2015	129,631	2,038	(107,791)	23,878
Loss for the nine month period	-	-	(18,528)	(18,528)
Other comprehensive income	-	(53)	-	(53)
Total comprehensive income	-	(53)	(18,528)	(18,581)
Share issues, net of transaction costs	18,010	-	-	18,010
Share based payments	-	1,530	-	1,530
Transfer of forfeited share based payments	-	(1,201)	1,201	-
At March 31, 2016	147,641	2,314	(125,118)	24,837

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

# **Consolidated Statement of Cash Flows**

FOR THE NINE MONTHS ENDED MARCH 31, 2016

	NINE MONTHS		
	Mar 2016	Mar 2015	
	<i>\$</i> ′000	\$'000	
Cash flows from operating activities			
Receipts from customers	298	249	
Research and Development Grants	-	2,318	
Interest received	176	448	
Payments to suppliers and employees	(18,930)	(8,515)	
Net cash used in operating activities	(18,456)	(5,500)	
Cash flows from investing activities			
Payments for property, plant and equipment	(206)	-	
Net cash used in investing activities	(206)		
Cash flows from financing activities			
Proceeds from issue of shares	19,462	310	
IPO and share issue transaction costs	(1,952)	-	
Net cash from financing activities	17,510	310	
Net (decrease)/ increase in cash and cash equivalents	(1,152)	(5,190)	
Cash and cash equivalents at beginning of the financial year	21,787	31,359	
Effects of exchange rate changes on cash and cash equivalents	(757)	648	
Cash and cash equivalents at end of period	19,878	26,817	

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

FOR THE NINE MONTHS ENDED MARCH 31, 2016

#### 1. BASIS OF PREPARATION OF THE CONSOLIDATED FINANCIAL REPORT

The condensed interim consolidated financial statements (the interim financial statements) of the Group are for the nine months ended March 31, 2016 and are presented in Australian dollars (\$), which is the functional currency of the parent company. These general purpose interim financial statements have been prepared in accordance with the requirements of the *Corporations Act 2001* and *AASB 134 Interim Financial Reporting*. They do not include all of the information required in annual financial statements in accordance with International Accounting Standards, and should be read in conjunction with the consolidated financial statements of the Group for the year ended June 30, 2015 and any public announcements made by the Group during the nine months in accordance with continuous disclosure requirements arising under the Australian Stock Exchange Listing Rules and the *Corporations Act 2001*.

The interim financial statements have been approved and authorised for issue by the Board of Directors on May 24, 2016.

#### (a) Basis of accounting

The nine month financial report is a general-purpose financial report, which has been prepared in accordance with the requirements of the Corporations Act 2001, applicable Accounting Standards including AASB 134 "Interim Financial Reporting" and other mandatory professional reporting requirements.

This financial report has been prepared on a going concern basis.

During the nine months ended March 31, 2016, the consolidated entity incurred a loss of \$18,528k (2015 comparative period: loss \$6,282k) and had net operating cash outflows of \$18,456k (2015 comparative period \$5,500k)

The ability of the Group to continue as a going concern has been determined by directors on the following basis:

- i. consistent with early stage biotechnology companies, the Group's operations are subject to considerable risks, primarily due to the nature of program development and commercialisation being undertaken; and
- ii. to allow the Group to execute its long term plans, it may be necessary to raise additional capital, and generate further income from commercialising the consolidated entity's intellectual property.

The financial report does not contain any adjustments to the amounts or classifications of recorded assets or liabilities that might be necessary if the Group does not continue as a going concern.

The financial statements take no account of the consequences, if any, of the effects of unsuccessful product development or commercialisation, nor of the inability of the Group to obtain adequate funding in the future.

The financial report has been prepared in accordance with the historical cost convention. For the purpose of preparing the financial report, the nine months has been treated as a discrete reporting period.

#### (b) Summary of significant accounting policies

The interim financial statements have been prepared in accordance with the accounting policies adopted in the Group's last annual financial statements for the year ended June 30, 2015.

FOR THE NINE MONTHS ENDED MARCH 31, 2016

#### (c) Estimates

When preparing the interim financial statements, management undertakes a number of judgements, estimates and assumptions about recognition and measurement of assets, liabilities, income and expenses. The actual results may differ from the judgements, estimates and assumptions made by management, and will seldom equal the estimated results.

The judgements, estimates and assumptions applied in the interim financial statements, including the key sources of estimation uncertainty were the same as those applied in the consolidated entity's last annual financial statements for the year ended June 30, 2015.

Grant revenue is generated through the Australian federal government's Research and Development Tax Incentive program, under which the government provides a cash refund for the 45% of eligible research and development expenditures. Because the grants are determined by the Australian government following the completion of a fiscal year based upon eligible research and development expenditures, grants are recorded in the fiscal year received, or anticipated to be received, (when a reliable estimate can be made) rather than the fiscal year to which they relate.

#### (d) Significant events and transactions

Key highlights of the interim reporting period to March 31, 2016 include the following:

#### Closed an Initial Public Offering in the United States with listing on the NASDAQ

In August, Benitec closed its U.S. initial public offering. The gross proceeds from the offering were A\$18.8 million (U.S.\$13.8 million), before deducting underwriting discounts and commissions and other offering expenses. Net proceeds from the offering will be used primarily to advance Benitec's therapeutic programs.

#### Acquired full rights to hepatitis B program and announced positive in vitro and in vivo data with HB-BB-331

In July, Benitec acquired the full rights to its pre-clinical ddRNAi-based hepatitis B therapeutic program which was previously a joint development between Benitec and Biomics. The initial collaboration allowed Benitec to make significant advances in the program. Based on promising *in vitro* data, Benitec made the decision to develop BB-HB-331 as a wholly owned pipeline program by acquiring Biomics' share in exchange for ordinary shares and cash consideration. Since acquiring full rights, Benitec has continued to progress the program.

#### Entered into a manufacturing services agreement with Lonza

In October, Benitec entered into a Manufacturing Services Agreement with Lonza Houston, Inc. to develop a scalable manufacturing process for Benitec's ddRNAi-based, Adeno-Associated Virus (AAV)-delivered products intended for therapeutic use in humans.

#### • Ceased further development of TT-034 for the treatment of hepatitis C

On February 26, 2016 the Company announced that it would wind-down its hepatitis C program and terminate the program upon completion of patients in Cohort 4 in its Phase I/IIa clinical trial for TT-034. Further detail on the termination of the program is included in 'in house Programs' earlier in this report.

Benitec is committed to completing the collection of trial data and monitoring patients through the required long-term safety follow-up period for the HCV trail. In addition, final data supporting the primary and secondary endpoints of the study will be reported in the last quarter of 2016 calendar year once the study is completed. Although the hepatitis C program has been discontinued, it is important to note that early stages of the TT-034 clinical trial indicated that TT-034 was safe and well tolerated, meeting the primary endpoint of the study and, as such, will assist in other programs.

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FOR THE NINE MONTHS ENDED MARCH 31, 2016

#### 2 REVENUE AND EXPENSES

		NINE MO	ONTHS
		March 2016	March 2015
(a)	Revenue	\$'000	\$'000
	(i) Sales Revenue		
	Licensing revenue and royalties	208	201
	(ii) Other revenue		
	Interest	177	448
		385	649
(b)	Other Income		
	Australian Government R&D Grants	3,600	2,318
	Net Foreign exchange gain	<u> </u>	558
		3,600	2,876
(c)	Expenses		
	Depreciation	66	28
	Share-based payments	1,530	1,035
	Foreign exchange loss	762	-

#### (d) Seasonality of Operations

There is no discernible seasonality in the operations of the consolidated entity.

#### 3. OPERATING SEGMENTS

#### **Business Segments**

The Group had only one business segment during the period, being the global commercialisation by licensing and partnering of patents and licences in biotechnology, with applications in biomedical research and human therapeutics.

#### **Geographical Segments**

Business operations are conducted in Australia. However there are controlled entities based in the USA and United Kingdom. The United Kingdom entity has no segment revenues, results or assets.

Segment Revenues from Geographical location External Customers Segment Results					Carrying Amount of Segment Assets		
	Mar 2016 \$'000	Mar 2015 \$'000	Mar 2016 \$'000	Mar 2015 \$'000	Mar 2016 \$'000	June 2015 \$'000	
Australia	208	201	(14,869)	(5,110)	26,359	24,893	
United States of America		-	(3,659)	(1,172)	706	627	
	208	201	(18,528)	(6,282)	27,065	25,520	

FOR THE NINE MONTHS ENDED MARCH 31, 2016

#### 3. OPERATING SEGMENTS (continued)

#### **Accounting Policies**

Segment revenues and expenses are directly attributable to the identified segments and include joint venture revenue and expenses where a reasonable allocation basis exists. Segment assets include all assets used by a segment and consist mainly of cash, receivables, inventories, intangibles and property, plant and equipment, net of any allowances, accumulated depreciation and amortisation. Where joint assets correspond to two or more segments, allocation of the net carrying amount has been made on a reasonable basis to a particular segment. Segment liabilities include mainly accounts payable, employee entitlements, accrued expenses, provisions and borrowings. Deferred income tax provisions are not included in segment assets and liabilities.

#### 4. EVENTS AFTER THE BALANCE SHEET DATE

There were no significant events after the March 31, 2016 balance date.

#### 5. CURRENT ASSETS – OTHER

	Consolidated	
	Mar 2016 \$'000	June 2015 \$'000
Prepayments	246	74
Prepaid clinical trials*	2,700	2,700
IPO costs **	-	285
Accrued Australian Government R&D Grants	3,600	-
Other current assets	12	95
	6,558	3,154

<sup>\*</sup> Benitec announced on June 3, 2013 its intention to progress its non-small cell lung cancer therapeutic into clinical development. Benitec advised it had reached agreement to use European-based clinical research organisation CTGCRO to manage clinical trials and negotiated favourable commercial terms which included prepayment for the clinical trial and consulting services. As a result of feedback from pharmaceutical companies and investors, the Company has recently decided to discontinue the non-small cell lung cancer program, allowing resources to be focused on developing the other preclinical programs. The non-small cell lung cancer program provided information into optimising ddRNAi design and delivery. The Company is currently negotiating with CTGCRO to apply the prepayment to support the development of other programs.

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<sup>\*\*</sup> IPO costs were incurred during the year for the public offer in the United States and the associated listing on the NASDAQ Global Select Market. These were held as a prepayment at June 30, 2015. They were subsequently transferred to equity once the capital raise to which they related was finalised.

FOR THE NINE MONTHS ENDED MARCH 31, 2016

	March 2016 \$'000	June 2015 \$'000
6. TRADE AND OTHER PAYABLES		
Trade creditors	1,816	760
Sundry creditors and accrued expenses	268	689
	2,084	1,449

#### 7. ISSUED CAPITAL

Details	Date	Number of Shares	Issue price (net of costs)	\$
Balance	30 June 2015	115,881,763		129,631,140
Biomics issue	15 July 2015	647,333	0.7724	500,000
IPO issue	15 August 2015	30,000,000	0.6488	19,462,643
IPO and share issue transaction costs		-		(1,952,886)
Balance	31 March 2016	146,529,096	·	147,640,897
The weighted average number of shares on issue during the				
nine months to March 31, 2016 was		140,912,079		

#### **Ordinary shares**

Ordinary shares entitle the holder to participate in dividends and the proceeds on the winding up of the Company in proportion to the number of and amounts paid on the shares held. The fully paid ordinary shares have no par value and the Company does not have a limited amount of authorised capital.

On a show of hands every member present at a meeting in person or by proxy shall have one vote and upon a poll each share shall have one vote.

#### Share buy-back

There is no current on-market share buy-back.

FOR THE NINE MONTHS ENDED MARCH 31, 2016

### 7. ISSUED CAPITAL (continued)

### Share options outstanding at 31 March 2016

		Exercise	Number
Grant date	Expiry date	price	under option
26 September 2011 *	26 September 2016	\$1.25	2,800,000
17 November 2011 **	17 November 2016	\$1.25	600,000
7 February 2012 **	7 February 2017	\$1.25	156,000
18 July 2012 **	18 July 2017	\$1.25	400,000
16 November 2012 **	16 November 2017	\$1.25	400,000
10 November 2013 *	18 May 2018	\$0.62	400,000
22 August 2013 **	22 August 2018	\$1.25	680,000
28 February 2014 ***	28 February 2019	\$1.26	13,246,203
15 May 2014 **	15 May 2019	\$1.50	180,000
17 December 2014 **	17 December 2019	\$1.25	3,034,000
6 May 2015 **	6 May 2020	\$1.25	650,000
20 August 2015 ****	21 August 2020	U.S. \$ 0.275	11,500,000
12 November 2015	12 November 2020	\$0.77	3,920,000
			37,966,203

<sup>\*</sup> Non-Executive Directors options

<sup>\*\*</sup> ESOP options

<sup>\*\*\*</sup> Unlisted options

<sup>\*\*\*\*</sup> Options converted to listed NASDAQ warrants, with one NASDAQ warrant representing 20 ordinary shares. Warrant" refers to a warrant to purchase one ADS at an exercise price of U.S.\$5.50 per ADS (the equivalent of 20 options over ordinary shares at U.S. \$0.275), exercisable from the date of issuance until five years thereafter.

FOR THE NINE MONTHS ENDED MARCH 31, 2016

#### 8. CONTINGENT LIABILITIES AND COMMITMENTS

On December 18, 2012, the Group announced the appointment of Synteract, Inc. as its Clinical Research Organisation responsible for the progression of TT-034 into Phase I/IIa clinical trials in the U.S.. The Group has negotiated a contract with favourable commercial terms, in some instances requiring prepayment, for Synteract to continue to manage the Phase I/IIa clinical trial and the follow-up clinical trial through 2016 and beyond.

Benitec announced on June 3, 2013 its intention to progress its non-small cell lung cancer therapeutic into clinical development. Benitec advised it had reached agreement to use European-based clinical research organisation CTGCRO to manage clinical trials and negotiated favourable commercial terms which included prepayment for the clinical trial and consulting services. As a result of feedback from pharma companies and investors, the Company has recently decided to discontinue the non-small cell lung cancer program, allowing resources to be focused on developing the other preclinical programs. The non-small cell lung cancer program provided information into optimising ddRNAi design and delivery. The Company is currently negotiating with CTGCRO to apply the prepayment against other programs.

On November 11, 2014, the Group entered into a Collaborative Research and License Agreement with 4D Molecular Therapeutics (4DMT) to identify and develop adeno-associated virus ("AAV") vector variants optimized for gene delivery to tissues within the eye using 4D technology and products combining such optimized AAV vector variants with Benitec's ddRNAi technology, for further development and commercialization by Benitec under license from 4D Molecular. Under this agreement the Group shall fund 4DMT for the studies to be carried out by 4DMT according to the research plan that was agreed between the parties.

The Group has contracted for scientific work on the therapeutic programs, as described above, and payments due within the next 12 months total approximately \$2,300,000 (December 31, 2015 \$2,320,000).

#### 9. RELATED PARTY TRANSACTIONS

#### Parent entity

Benitec Biopharma Limited is the parent entity.

#### Key management personnel

Disclosures relating to key management personnel are set out in 30 June 2015 Annual Report in the remuneration report.

#### Other transactions with key management personnel and their related parties

Payments totalling \$67,906 were made to Francis Abourizk Lightowlers (a law firm in which Peter Francis is a partner and has a beneficial interest) for legal services at normal commercial rates in the nine months to March 31, 2016 (nine months ended March 31, 2015: \$80,672).

Consultancy fees totalling \$113,559 were paid for executive duties in the nine months to March 31, 2016 (nine months ended March 31, 2015: \$42,000) to Newstar Ventures Ltd, a corporation in which John Chiplin is a director and has a beneficial interest.

#### Receivable from and payable to related parties

There were no trade receivables from or trade payables to related parties at the current and previous reporting date

#### Loans to/from related parties and Terms and conditions

There were no loans to or from related parties at the current and previous reporting dates. All transactions were made on normal commercial terms and conditions and at market rates.

# Management's discussion and analysis of financial condition and review of operations

#### **Operating Results**

We are a clinical-stage biotechnology company with a pipeline of in-house and partnered therapeutic programs based on our patented gene-silencing technology, ddRNAi. We are developing treatments for chronic and life-threatening human diseases such as hepatitis B, age-related macular degeneration and oculopharyngeal muscular dystrophy based on this technology. In addition, we have licensed ddRNAi technology to other biopharmaceutical companies that are progressing their programs towards, or are in, clinical development for applications, including HIV/AIDS, retinitis pigmentosa, Huntington's disease, cancer immunotherapy and intractable neuropathic pain.

Our focus has been validating our ddRNAi platform technology, including the Phase I/IIa clinical trial of TT-034, a therapy for hepatitis C. We reported in February 2016 our plans to discontinue the TT-034 program for commercial reasons. Early stages of the clinical trial indicated TT-034 was safe and well-tolerated in the nine patients dosed in the clinical trial. The success of this "first in human" trial is a key step in validating ddRNAi for therapeutic use, providing the opportunity to progress Benitec's other in-house programs in similar manner, applying the key lessons learned by advancing TT-034 to the clinic. In the near future, we expect to earn revenue from partnering in-house programs with biotechnology and pharmaceutical companies, forming strategic collaborations with pharmaceutical companies, and out-licensing the ddRNAi platform for therapeutic areas outside of the Company's in-house pipeline. There can be no assurance, however, as to whether we will enter into any additional such arrangement or what the terms of any such arrangement could be.

During the first part of 2016 the Company focused on internal changes to position it for future success. This included an in-depth review of its scientific pipeline to ensure efforts are focused on those areas with a high probability of return on investment and commercial success. In parallel to this review and reprioritisation of programs, the Company restructured and consolidated internal and external resources to reduce annual expenses and extend the cash runway. Project management practices have been enhanced to ensure that future activities are outcome driven and that there is improved control over timelines, deliverables and cash management.

We have incurred losses from operations in each year since inception. Our net loss in the 9 months to March 31, 2016 was A\$18.5 million and in the previous corresponding period to March 31, 2015 A\$6.3 million. Our net losses were A\$11.5 million, A\$7.0 million and A\$3.5 million for the fiscal years ended June 30, 2015, 2014 and 2013, respectively. The majority of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years and over future fiscal years we expect our expenses will increase substantially in connection with our ongoing activities as we:

- pursue clinical proof of concept across our programs, including treatments for hepatitis B, AMD and OPMD;
- continue preclinical development of cell therapy and immunotherapy programs through preclinical proof of concept;
- continue our research and development efforts for the refinement of ddRNAi-based technology;
- seek regulatory approval for our product candidates; and
- add additional personnel and resources to support our product development and commercialisation efforts.

We may generate revenue from licensing programs, strategic alliances or collaboration arrangement with pharmaceutical companies. These arrangements are likely to be more appealing to them when our pipeline is more advanced. We do not expect to generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years, is subject to significant uncertainty and may never occur.

# Management's discussion and analysis of financial condition and review of operations (continued)

We will continue to pursue licensing programs, strategic alliances and collaboration arrangements with pharmaceutical companies and we regard this as our key value creation opportunity unless and until we are able to gain regulatory approval for one of our product candidates and decide to commercialise it ourselves. If we were to decide to take one or more product candidates to commercialization on our own, the process of obtaining regulatory approval for the selected programs and building the commercial infrastructure that would be necessary to commercialise them, if approved, would require substantial additional funding.

Our current operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. These additional funds could be raised through public or private equity or debt financings (although debt financings are unlikely to be available until we have significant revenue and cash flow to service debt we may incur), government or other third-party funding, strategic alliances and licensing arrangements or a combination of these approaches. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favourable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and compromise our ability to develop our product candidates and pursue our strategy.

We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. Because of the numerous risks and uncertainties associated with product development in our field, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to generate product revenue or achieve or maintain profitability. Our ability to generate revenue from licensing, strategic alliances and collaboration arrangements and product sales will depend on a number of factors, including, among others, obtaining and maintaining adequate coverage and reimbursement from third-party payors for any of our product candidates that may receive regulatory approval. Even if we are able to generate revenues from licensing programs, strategic alliances or collaboration arrangements or commercial sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and we could be forced to reduce our operations.

# **Financial operations overview**

#### Revenue

To date, we have derived revenues from licensing fees, the Australian federal government's Research and Development Tax Incentive program and interest income. We have not generated any revenues from the sales of products. Revenues from licensing fees and the tax incentive program are included in the revenue line item on our statements of profit or loss.

Our licensing fees have been generated through the licensing of our ddRNAi technology to biopharmaceutical companies.

Our grant revenue is generated through the Australian federal government's Research and Development Tax Incentive program, under which the government provides a cash refund for the 45% of eligible research and development expenditures, including salaries, by small Australian entities having a tax loss. For this purpose, small Australian entities are defined as those with less than A\$20 million in revenue. This grant is available for our research and development activities in Australia, as well as activities in the United States to the extent such US-based expenses relate to our activities in Australia, do not exceed half the expenses for the relevant activities and are approved by the Australian government. Because the grants are determined by the Australian government following the completion of a fiscal year based upon eligible research and development expenditures, grants are recorded in the fiscal year received, or anticipated to be received (when a reliable estimate can be made) rather than the fiscal year to which they relate.

We also record interest and other financial income earned from bank accounts, term deposits and short-term investments as other revenue in our statements of profit or loss.

# Financial operations overview (continued)

#### **Employment related costs**

Employment related costs include salaries for all our employees and related benefits, including the grant of share options, which are valued and included in the statements of profit or loss and other comprehensive income as share based expenses.

#### **Impairment**

We assess at the end of each fiscal year and half year whether there is an indication that an asset may be impaired. If any such indication exists, or when annual impairment testing is required for an asset, such as goodwill, intangible assets with indefinite useful lives and intangible assets not yet available for use, we make an estimate of the asset's recoverable amount. An asset's recoverable amount is the higher of its fair value less costs to sell and its value in use and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets and the asset's value in use cannot be estimated to be close to its fair value. In such cases, the asset is tested for impairment as part of the cash generating unit to which it belongs. When the carrying amount of an asset or cash-generating unit exceeds its recoverable amount, the asset or cash-generating unit is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Impairment losses relating to continuing operations are recognized in those expense categories consistent with the function of the impaired asset unless the asset is carried at revalued amount (in which case the impairment loss is treated as a revaluation decrease).

#### Royalties and license fees

Benitec pays royalties and license fees in connection with our licensing of intellectual property from third parties. In connection with our acquisition of Tacere in 2012, we agreed to pay to the former shareholders of Tacere royalties on certain licensing revenue earned by us through the license of certain products, including TT-034, covered by a patent controlled by Tacere in October 2012. Any such royalties would be calculated as follows: 15% if the license is entered into prior to commencement of a Phase III clinical study and 2.5% if the license is entered into after commencement of a Phase III clinical study. Also, if we were to directly sell these products, then we would pay a royalty of 2.5% on net sales to the former shareholders of Tacere.

In August 2009, Benitec entered into a collaborative agreement with Biomics Biotech Co., Ltd., or Biomics, pursuant to which we agreed to share any revenue generated from commercializing our jointly filed patents which relate to single-stranded RNA and shRNA sequences for treatment of hepatitis B. In July 2015, we entered into an earn-out agreement with Biomics pursuant to which we acquired all rights, title and interest in these patents in exchange for upfront and milestone payments. At the time of signing the agreement, we paid Biomics A\$2.5 million consisting of A\$2.0 million in cash and 647,333 ordinary shares (having a value of A\$500,000 at the time the agreement was entered into). These shares could not be traded until October 1, 2015 and thereafter Biomics may only sell up to A\$100,000 in value of those shares in any calendar month. Upon out-licensing a patent in this patent family we will also pay Biomics 50% of the initial licensing revenue received by us up to a maximum of A\$3.5 million and, in the event we receive licensing revenue greater than a\$6 million, we would pay Biomics 1.5% of licensing revenue on any such additional amounts.

In August 2013, Benitec entered into a commercial license arrangement with NewSouth Innovations Pty Limited, or NSi, of University of New South Wales for the patent portfolio relating to our therapy product candidate for NSCLC. The license provides for modest up-front and ongoing license fees, and also milestone and single digit percentage royalty payments on net sales. A percentage of sub-licensing revenue is also payable to NSi. We may terminate the license at will, and in the event of certain breaches by NSi. NSi may terminate the license in the event of certain breaches by Benitec. Although Benitec recently decided to discontinue the NSCLC program, the license has not been terminated by either party.

# Financial operations overview (continued)

#### Foreign exchange translation

The foreign currency translation reserve represents the currency translation movements of subsidiary company balances denominated in foreign currencies at year end. Foreign currency monetary items are translated at the period exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined. Movements in the foreign currency translation reserve are shown in our Statement of Profit or Loss and Other Comprehensive Income.

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transactions. Exchange rate differences are recognized in the Statement of Profit or Loss and Other Comprehensive Income.

### **Critical Accounting Policies and Estimates**

The preparation of our financial statements requires us to make estimates and judgments that can affect the reported amounts of assets, liabilities, revenues and expenses, as well as the disclosure of contingent assets and liabilities at the date of our financial statements. We analyse our estimates and judgments and we base our estimates and judgments on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may vary from our estimates. Our significant accounting policies are described in note 1 to these periodic financial statements and are detailed in Note 1 to our consolidated financial statements for the fiscal year ended June 30, 2015 (which are available on the company website and at ASX:BLT NASDAQ: BNTC; NASDAQ: BNTCW). We have summarised below the accounting policies of particular importance to the portrayal of our financial position and results of operations and that require the application of significant judgment or estimates by our management.

#### Share-based payments transactions

We measure the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using a Black-Scholes model.

#### Tax losses

Given our history of recent losses, we have not recognised a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether we or our subsidiaries will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilized. We note that the availability of tax losses is subject to an Australian continuity of ownership test or, if we fail that test, the same business test. If we continue to obtain funding from new shareholders, then we may not comply with the continuity of ownership test.

#### Certain differences between IFRS and U.S. GAAP

IFRS differs from U.S. GAAP in a few respects. While we have not assessed the materiality of differences between IFRS and U.S. GAAP, we note in particular that IFRS permits the recording of finance income and research and development grants as revenue, unlike U.S. GAAP, under which interest and other finance income would not be recorded as revenue but instead as net finance income and research and development grants would be recorded as an offsetting reduction to research and development expenses. In addition, under IFRS, all employment-related expenses are reported in their own line item in our Statement of Profit or Loss and Other Comprehensive Income, unlike U.S. GAAP, under which employment-related expenses are generally allocated to line items such as research and development expense or general and administrative expense based on the functions performed by each applicable employee.

The following discussion relates to our consolidated results of operations, financial condition and capital resources. You should read this discussion in conjunction with our consolidated financial statements and the notes thereto contained elsewhere in this report.

# **Results of Operations**

# A. Comparison of the nine months ended March 31, 2016 to the nine months ended March 31, 2015

Our initial public offering in the United States was completed after the end of fiscal year 2015. The capital we raised in fiscal year 2014 continued to allow us to progress our research and development efforts in fiscal 2015.

#### Revenue

	For the nine months ended March 31		Increase
	2016 \$'000	2015 \$'000	(Decrease) \$'000
Revenue:			
Licensing revenue and royalties	208	201	7
Other Revenue:			
Finance income – interest	177	448	(271)
Other Income:			
Australian Government R&D Grants	3,600	2,318	1,282
Net foreign exchange gain*	-	558	(558)

Licensing revenue and royalties increased very slightly from the nine months ended March 31, 2015 to the nine months ended March 31, 2016 primarily due to timing differences in the recognition of such revenue.

Finance income decreased by A\$0.2 million from A\$0.4 million in the nine months ended March 31, 2015 to A\$0.2 million in the nine months ended March 31, 2016, as a result of holding cash in low yielding U.S. dollar bank accounts.

\* Net foreign exchange gain is due to a high U.S. dollar cash balance in fiscal 2015 following an equity placement in April 2014, coupled with a significant appreciation of the U.S. dollar against the Australian dollar calendar 2015. The net foreign exchange loss in the nine months to March 31, 2016 of A\$0.8 million reflect the adverse currency movement on the cash held in U.S. dollars. The significant increase in the Australian Government R&D claim reflects the increased eligible expenditure on R&D in fiscal 2015.

#### Expenses

Research and development expense. Research and development expense increased by A\$6.9 million, from A\$4.2 million in the nine months year March 31, 2015 to A\$11.1 million in the nine months ended March 31, 2016, primarily due to:

- acquiring for A\$2.5 million, the full rights to its pre-clinical ddRNAi-based hepatitis B therapeutic program which was previously a joint development collaboration between Benitec and Biomics;
- the higher research and development activity in 2015, including the dosing of patients in our Phase I/IIa clinical trial for TT-034; and
- the execution of an agreement with 4D Molecular Therapeutics LLC, or 4DMT, to develop vectors.

Employment related expenses. Employment-related expenses increased by A\$2.6 million, in the nine months ended March 31, 2016 compared to the nine months ended March 31, 2015, due to increased staff levels, particularly at Tacere's laboratory, in 2015.

Share based expenses. Share based expenses increased by A\$0.5 million, from A\$1 million in the nine months ended March 31, 2015 to A\$1.5 million in the nine months ended March 31, 2016 largely due to the Share based expense costs for options granted to Directors on November 12, 2015 at the Company's Annual General Meeting. Share based expenses are calculated using a Black-Scholes model. The share based expense model uses a data set that includes share price and exercise price, exercise probability, volatility, exercise time and interest rates. Variation in these factors and an increased level of option grants to staff were the major contributors to this expense increase. We recognize share based expenses over the service period in which the employee earns the award, which is the vesting period of the award.

Travel related costs. Travel related costs increased by A\$0.1 million from A\$0.8 million in the nine months ended March 31, 2015 to A\$0.9 million in the nine months ended March 31, 2016 due to travel related to the IPO, an increase in staff levels and more participation in international conferences, in addition to meetings with pharmaceutical companies.

Consultants' costs. Consultants' costs increased by A\$0.3 million from A\$0.6 million in the nine months ended March 31, 2015, to A\$0.9 million in the nine months ended March 31, 2016. We retain specialist advisers in relation to our key product candidate programs and for media and shareholder relations capabilities.

Occupancy costs. Occupancy costs increased from A\$0.2 million in the nine months ended March 31, 2015 to A\$0.4 million in the nine months ended March 31, 2016 due to a new expanded lease for the laboratory in California and increased space under lease in Australia.

Corporate expenses. Corporate expenses increased from A\$0.6 million in the nine months ended March 31, 2015 to A\$0.9 million in the nine months ended March 31, 2016 due to an increase in the size of our company and increases in consequent expenses.

*IPO costs.* We expensed legal, accounting and other costs of A\$1.0 million in the nine month period in relation to our US initial public offering which was completed in August 2015.

Loss for the period

As a result of the foregoing, our loss for the period after tax benefit increased by A\$12.2 million from A\$6.3 million in the nine months ended March 31, 2015 to A\$18.5 million in the nine months ended March 31, 2016.

Given our and our subsidiaries' history of recent losses, we have not recognized a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether we or our subsidiaries will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilized.

#### B. Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 1995, and as of June 30, 2015 we had accumulated losses of A\$107.8 million and at March 31, 2016 we had accumulated losses of A\$125.1 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding and other collaborations, strategic alliances and licensing arrangements.

We have had no borrowings in fiscal 2013, fiscal 2014, fiscal 2015 or in this nine months to March 31, 2016 and do not currently have a credit facility.

As at March 31, 2016 we had cash and cash equivalents of A\$19.9 million (June 30, 2015 A\$21.8 million). Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash and cash equivalents are held in bank accounts. Our short-term investments consist of term deposits with maturity within 180 days.

#### **Operating capital requirements**

To date, our sources of liquidity have been licensing revenue and royalties, Australian government research and development grants, interest on invested cash in excess of immediate requirements and proceeds of the issuance of equity securities.

In the future, we expect our revenue stream will be generated mostly from licensing, strategic alliances and collaboration arrangements with pharmaceutical companies. While we continue to progress discussions and advance opportunities to engage with pharmaceutical companies and continue to seek licensing partners for ddRNAi in disease areas that are not our focus, there can be no assurance as to whether we will enter into such arrangements or what the terms of any such arrangement could be.

While we have established some licensing arrangements, we do not have any products approved for sale and have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates.

Unless and until we establish significant revenues from licensing programs, strategic alliances or collaboration arrangements with pharmaceutical companies, or from product sales, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of product candidates and begin to prepare to commercialize any product that receives regulatory approval. We are subject to the risks inherent in the development of new gene therapy products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies for our product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- revenue received from commercial sales of any of our product candidates that may receive regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defence and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we need to in-license or acquire other products and technologies.

### C. Research and Development, Patents and Licenses, etc.

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses incurred under agreements with academic research centres, clinical research organizations and investigative sites that conduct our clinical trials; and
- the cost of acquiring, developing, and manufacturing clinical trial materials.

Research and development expenses do not include employment related expenses, which are included in our Statement of Profit or Loss and Other Comprehensive Income as a separate line item.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future product development, preclinical studies or clinical trials of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical trials and other research and development activities;
- the countries in which trials are conducted;
- future clinical trial results;
- uncertainties in clinical trial enrolment rates or drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required to complete clinical development of a product candidate or if we experience significant delays in enrolment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of ddRNAi product candidates and explore further potential applications of our technology.

# D. Trend Information

Our objective is to become the leader in discovering, developing, clinically validating and commercializing ddRNAi-based therapeutics for a range of human diseases with high unmet clinical need or large patient populations, and to thereby provide a better life for patients with these diseases. Our strategy to accomplish this goal is to progress our pipeline of proprietary ddRNAi-based therapeutics, continue our leadership position in ddRNAi-based therapeutics, develop drugs in our core disease area, partner selectively to commercialize and expand our pipeline and pursue indications with high unmet medical need or a large patient population.

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The scientific research that forms the basis of our efforts to develop product candidates is based on the therapeutic use of ddRNAi, and the identification, optimization and delivery of ddRNAi-based product candidates is relatively new. The scientific evidence to support the feasibility of successfully developing therapeutic treatments based on ddRNAi is preliminary and limited. There can be no assurance that any development and technical problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

We are currently working to advance our product candidates for hepatitis B and OPMD through completion of preclinical *in vivo* proof of concept studies and to submission of IND applications; and to advance our product candidate for AMD through completion of pre-clinical proof of concept studies, submission of an IND application and initiation of a clinical trial. We intend to advance our product candidates for hepatitis B and OPMD into clinical trials, with additional financing. Although we have decided to terminate our hepatitis C program, we are currently completing our Phase I/IIa clinical trial for hepatitis C.

#### E. Off-Balance Sheet Arrangements.

We did not have over the past three fiscal years and this nine months year to March 31, 2016, and we currently do not have, any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

### **Risk Factors**

In addition to the other information set forth in this Quarterly Report, you should carefully consider the factors discussed in "Risk Factors" in our Annual Report on Form 20-F for the fiscal year ended June 30, 2015. The risks disclosed in our Annual Report on Form 20-F could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 20-F are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition or operating results in the future.

# **Directors' Declaration**

### FOR THE NINE MONTHS ENDED MARCH 31, 2016

In the opinion of the Directors of Benitec Biopharma Limited:

- (a) the consolidated financial statements and notes of Benitec Biopharma Limited are in accordance with the *Corporations Act 2001*, including
  - i. giving a true and fair view of its financial position as at March 31, 2016 and of its performance for the quarter ended on that date; and
  - ii complying with Accounting Standard AASB 134 Interim Financial Reporting; and
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the directors:

**Peter Francis** 

Director

Melbourne, May 24, 2016



Level 17, 383 Kent Street Sydney NSW 2000

Correspondence to: Locked Bag Q800 QVB Post Office Sydney NSW 1230

T +61 2 8297 2400 F +61 2 9299 4445 E info.nsw@au.gt.com W www.grantthornton.com.au

# Independent Auditor's Review Report To the Members of Benitec Biopharma Limited

We have reviewed the accompanying nine months financial report of Benitec Biopharma Limited ("Company"), which comprises the consolidated financial statements being the statement of financial position as at 31 March 2016, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the nine months ended on that date, notes comprising a statement or description of accounting policies, other explanatory information and the directors' declaration of the consolidated entity, comprising both the Company and the entities it controlled at the nine month year end or from time to time during the nine month period end.

# Directors' responsibility for the nine months financial report

The directors of Benitec Biopharma Limited are responsible for the preparation of the nine month period financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such controls as the directors determine is necessary to enable the preparation of the nine month period financial report that is free from material misstatement, whether due to fraud or error.

#### **Auditor's responsibility**

Our responsibility is to express a conclusion on the nine month period financial report based on our review. We conducted our review in accordance with the Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the nine month period financial report is not in accordance with the Corporations Act 2001 including: giving a true and fair view of the Benitec Biopharma Limited consolidated entity's financial position as at 31 March 2016 and its performance for the nine months ended on that date; and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Benitec Biopharma Limited, ASRE 2410

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requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a nine month period financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Independence

In conducting our review, we complied with the independence requirements of the Corporations Act 2001.

#### Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the nine month period financial report of Benitec Biopharma Limited is not in accordance with the Corporations Act 2001, including:

- a giving a true and fair view of the financial position as at 31 March 2016 and of its performance for the nine months ended on that date; and
- b complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.

GRANT THORNTON AUDIT PTY LTD

Chartered Accountants

N/J Bradley

Partner - Audit & Assurance

Sydney, 24 May 2016